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WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 26, 2022

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MEMORANDUM

SUBJECT: **Broflanilide:** Ecological Risk Assessment for IR-4 Proposed Section 3 New Uses in and Around Poultry Houses and Facilities

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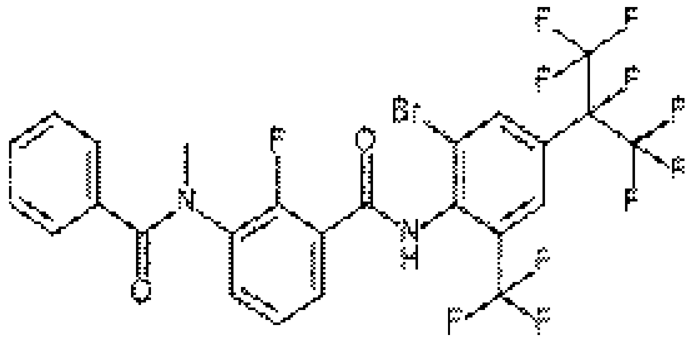
The Environmental Fate and Effects Division (EFED) has completed an ecological risk assessment for a proposed Section 3 New Use (S3NU) of broflanilide (CAS Registry Number: 1207727-04-5; PC Code: 283200) inside and around poultry houses and facilities.

Ecological Risk Assessment for Proposed New Uses of Broflanilide In and Around Poultry Facilities



N-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(*N*-methylbenzamido)benzamide
CAS No. 1207727-04-5
USEPA PC Code: 283200

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1 Executive Summary

1.1 Overview

Broflanilide is a diamide insecticide that has larvicidal activity against many chewing pests (wireworm, maggot, root worm, *etc.*,), and broflanilide's fate characteristics and the propensity to sorb to sediments suggest that it is not likely systemic in plants. Broflanilide is being proposed for use as a spray in and around poultry houses and facilities to control darkling beetles which is mostly found on the perimeter portions of floors and lower walls, near feeders and water lines. For the proposed poultry house use, the poultry litter collected from the broiler house could potentially be used as a soil amendment to agricultural crops after it has been treated with broflanilide.

1.2 Risk Conclusions Summary

Table 1-1 summarizes potential risks associated with the use of broflanilide. In short, There is a potential for direct adverse effects to terrestrial and aquatic invertebrates, and because of the persistence of broflanilide in sediments these risks are likely to increase with annual reapplications

For aquatic organisms, acute and chronic water column estuarine/marine invertebrate endpoints from the mysid studies resulted in RQs that exceed acute and chronic LOCs based on modeled water column EECs. Similarly, all sub-acute and chronic endpoints for three species of freshwater and estuarine benthic invertebrates are exceeded by modeled EECs, therefore there are risks identified for all invertebrates that interact with sediments in aquatic habitats. Because the modeling suggests that broflanilide will accumulate in the sediments over a period of time, these RQs reflect the risks associated with that accumulation, highlighting an increased risk to invertebrates that interact with aquatic sediments due to the sediment adsorption of broflanilide. LOCs for water column freshwater invertebrates are not exceeded, based on water column comparisons to the available acute and chronic *Daphnia* endpoints. Estuarine mollusk (eastern oyster) acute data suggest low risk to mollusks when compared to modeled estimated environmental concentrations (EEC). There are no level of concern (LOC) exceedances for freshwater or estuarine/marine fish, nor for aquatic plants.

For terrestrial organisms, acute and chronic RQs for adult and larval honey bees exceeded the LOCs from perimeter spray applications indicating risk to terrestrial invertebrates. This was supported by modeled EECs exceeding the acute contact and oral toxicity endpoints for bumblebees. For perimeter sprays, while there are inherent risks to terrestrial invertebrates, they are likely limited to the direct application areas which likely have less vegetation available because of perimeter management, and thus a lower potential for contamination of pollen and nectar. Since broflanilide is persistent in soils, any non-target terrestrial invertebrates, including bees that come into contact with or consume terrestrial sediments (*e.g.*, ground dwelling/nesting bees), are at risk from the proposed uses. Because of the persistence of broflanilide in sediments, the risks to sediment dwelling/interacting invertebrates would increase with every subsequent use of broflanilide. However, exposure to honeybees from poultry manure applications are unlikely given manure is applied as a solid and not a liquid spray, and there is evidence to suggest that broflanilide's propensity to sorb to lipids and sediments indicate that it is not likely systemic in plants and therefore exposure to bees through pollen and nectar contamination is unlikely. There are chronic risk concerns for birds and mammals consuming broflanilide contaminated aquatic organisms. There is low potential for effects on birds and mammals on an acute and chronic exposure basis through diet from the proposed uses of broflanilide as a spray application to the perimeter of poultry houses and from poultry manure applications to agricultural fields. Additionally, risks to terrestrial plants are considered low.

1.3 Environmental Fate and Exposure Summary

Broflanilide has a low solubility limit in water (0.71 mg/L at 20°C) and has low mobility in soil and sediment. Its vapor pressure of 6.6×10^{-11} torr and Henry's law Constant of 3.0×10^{-14} atm-m^3/mol suggest volatilization is not a major dissipation pathway. Broflanilide is persistent in terrestrial and aquatic environments. Broflanilide is stable to hydrolysis and soil photolysis. Under anaerobic and aerobic conditions, the chemical persists in soil and water bodies, with microbial metabolism half-lives on the orders of months to years. There were no major (>10% of applied radioactivity (AR)) degradation products formed in laboratory studies but several minor transformation products were detected in soil. Major routes of dissipation are expected to be photodegradation and runoff of eroded sediment containing broflanilide and its degradates.

The Log Kow of 5.2 at pH 4 and 7 suggests broflanilide has the potential for bioaccumulation. The bioconcentration factors in rainbow trout whole fish tissues are 266-364X. Depuration half-lives were less than 3 days in all matrices, with >95% of the total residues accumulated during 28 days of exposure eliminated in 10 days.

The overall stability/persistence profile for broflanilide suggests that it has potential to accumulate in soil and aquatic environments with each successive application. In other words, repeated use can considerably increase risks over time due to the persistence of broflanilide in aquatic environments.

Four experimental studies (MRID 51780501-04) were submitted with this action. Preliminary reviews of these studies describe a lower (2-4 ton/A; MRID 51780501) poultry litter amendment rate and indicate that broflanilide degrades slowly (half-life = 453 days; MRID 51780502) and has limited bioavailability (MRIDs 51780503-04) in poultry litter. These findings are consistent with the behavior of broflanilide in other environmental media (*e.g.*, soil and sediments).

1.4 Ecological Effects Summary

Fish

The ecological effects database is incomplete for chronic exposures to freshwater fish. Typically, an acute to chronic ratio would be used to estimate the NOAEC for this taxon: however, in this case the acute fathead minnow and sheepshead studies did not result in definitive LC_{50} values and had little mortality. This uncertainty has little impact on the evaluation of risk for freshwater fish because the EECs are orders of magnitude below the lowest available endpoints for acute or chronic data, suggesting that any new chronic endpoint would need to be more toxic by orders of magnitude to result in a risk conclusion. Therefore, the absence of these data have little impact on the risk conclusions for fish and therefore additional chronic data for freshwater fish are not needed.

Water Column Invertebrates

Acute freshwater invertebrate data testing daphnia (*Daphnia magna*) and estuarine/marine mollusks, eastern oysters (*Crassostrea virginica*), showed no effects up to the highest tested concentrations. In contrast, an acute study with mysids resulted in a LC_{50} of 0.0215 µg a.i./L. Based on the mysid data, broflanilide is classified as very highly toxic to estuarine and marine invertebrates. Chronic *Daphnia* and mysid toxicity studies showed at low concentrations statistically significant differences compared to the controls. The Daphnia NOAEC of 5.93 µg a.i./L was based upon 6-8% reductions in length, total offspring, birth rate, and time to first brood at 11.6 µg a.i./L. The mysid study did not establish a definitive NOAEC endpoint because at the lowest test concentration, 0.0018 µg a.i./L, there was 17% reduced survival for F1 and 22% reduced offspring per female. The lack of a definitive NOAEC for the mysid is an uncertainty in the risk conclusions. Given the robust dataset for benthic invertebrates, the predominant sediment pathway of exposure, and the magnitude of the exceedance of the lowest test concentration in the mysid study by the EECs, there is little doubt about the potential risks to aquatic invertebrates from the proposed uses. Therefore, while the guideline requirement remains to be fulfilled, the impact on the conclusions of risks of concern in this assessment is considered low and an additional chronic mysid study is not needed.

Benthic Invertebrates

Three sub-chronic (10-day) toxicity studies on benthic invertebrates were submitted. Studies with freshwater species *Chironomus dilutus* and *Hyalella azteca*, and an estuarine/marine species, *Leptocheirus plumulosus,* resulted in LC_{50} values of 9.99, 13.5, and 14 µg ai/kg-dry sediment. Chronic toxicity studies with these three species are also available. In a 60-day static-renewal sediment test with *Chironomus dilutus*, the overall NOAEC was 1.5 µg ai/kg-dry sediment based on 20% reduced survival and 36% reduced percent emergence. In a 42-day reproduction study on *Hyalella azteca* the overall NOAEC was non-definitive (< 1.7 µg ai/kg-dry sediment) based on a 46% reduction in male to female ratio. NOAECs were also determined for survival (6.7 µg ai/kg-dry sediment; >20% reductions) and reproduction (3.3 µg ai/kg-dry sediment; >45% reductions). In a 28-day spiked sediment test with *Leptocheirus plumulosus*, the NOAEC was determined to be 3.8 µg ai/kg-dry sediment based on 12% reduced survival at the LOAEC.

Aquatic plants

Data show limited to no toxicity at EECs far greater than those estimated for perimeter spray applications and manure applications.

Birds/Terrestrial Phase Amphibians/Reptiles

Acute oral toxicity tests of TGAI with bobwhite quail (*Colinus virginianus*), mallard duck (*Anas platyrhynchos*), and canary (*Serinus canaria*) reported no effects in response to broflanilide at 2000 mg a.i./kg-bw. No mortalities or sublethal effects were observed in subacute dietary toxicity studies with bobwhite quail or mallard duck (LC_{50} s are >5000 mg a.i./kg-diet). Based on these data, broflanilide is classified as practically non-toxic to birds, and their surrogate taxa (*i.e.*, reptiles and terrestrial-phase amphibians) on an acute oral or subacute dietary exposure basis. A reproduction study with mallard ducks resulted in reduced eggs laid and 14% reduction in surviving hatchlings at 87.4 mg a.i./kg-diet (NOAEC = 29.7 mg a.i./kg-diet). A reproduction study with bobwhite quail showed significant (5-6%) inhibitions in 14-day survivors/hatchling at 506 and 1021 mg ai/kg-diet treatment groups, and in 14-day survivor weight at 1021 mg ai/kg-diet (NOAEC = 254 mg a.i./kg-diet).

Mammals

An acute oral toxicity study with rats (*Rattus norvegicus*) reported no chemical related effects at the highest tested concentration (LD_{50} > 5000 mg a.i./kg-bw). Therefore, broflanilide is considered practically non-toxic to mammals on an acute oral exposure basis. In a two-generation reproduction study with rats, there were no observed effects related to growth or survival of adults; however decreased pup weights were observed in both male and female F1 pups (5-7%) and this increased in F2 pups (6-10%) at the LOAEL (1500 mg a.i./kg-diet) and at 15,000 mg a.i./kg-diet (NOAEC = 300 mg a.i./kg-diet).

Terrestrial Invertebrates (Bees)

Broflanilide is highly toxic to honey bees (*Apis mellifera*) and bumble bees (*Bombus terrestris*) on both an acute contact and oral exposure basis. In an acute (single dose) contact and acute oral combined toxicity study with adult honey bees (*Apis mellifera*), the 48-hr contact LD_{50} = 0.0088 µg a.i./bee and acute oral LD_{50} = 0.0149 µg a.i./bee. Two additional acute oral and acute contact toxicity studies on adult honey bees with technical grade active ingredient (*i.e.*, broflanilide technical; TGAI) and a typical end-use product (TEP; 9.6% a.i.) reported acute contact LD_{50} values from 0.012 to 0.017 µg a.i./bee and acute oral LD_{50} values ranging from 0.045 to 0.0693 µg a.i./bee. Additional broflanilide toxicity studies were conducted using TGAI and TEP (9.6% a.i.) with bumblebees, resulting in contact LD_{50} values of >0.120 and 0.122 µg a.i./bee respectively, and acute oral LD_{50} values of 0.0195 and 0.0139 µg a.i./bee respectively. An acute larval honey bee toxicity study conducted with TGAI resulted in an 8-day LD_{50} of >0.029 µg a.i./larva/day. Mortality (36%) was observed at the highest tested concentration of 0.029 µg a.i./larva/day. Based on these results, broflanilide is considered very highly toxic to adult and larval bees. A 10- day chronic (repeat dose) TGAI toxicity test with adult honeybees resulted in a NOAEL of 0.00062 µg a.i./bee/day and a LOAEL of 0.0011 µg a.i./bee/day based on 30% mortality. The next two doses 0.00237 and 0.0049 µg a.i./bee/day resulted in 93 and 100% mortality. A 22-day chronic larval honeybee toxicity test conducted with TGAI resulted in a NOAEC of 0.000080 µg a.i./larva/day based on 18% larval mortality at 0.00027 µg a.i./larva/day.

Terrestrial Plants

Data for terrestrial plants show limited to no toxicity at EECs far greater than those estimated for perimeter spray applications and manure applications.

1.5 Identification of Data Needs

The ecological effects database is incomplete for freshwater fish and estuarine/marine invertebrates based on EFED's 2020 Section 3 New Chemical (S3NC) ecological risk assessment (ERA) (DP 445689), but they are not considered high value:

- **Guideline 850.1400**. The chronic freshwater fish study did not use the most sensitive species (*e.g.*, bluegill or rainbow trout) based on acute toxicity. Therefore, there is uncertainty regarding the protectiveness of the available endpoint. Acute to Chronic Ratios (ACRs) are often used to estimate chronic endpoints for missing data such as this; however, the available freshwater fish data are not suitable to generate an ACR for broflanilide. Exposure estimates in the new chemical assessment (USEPA 2020, DP 445689) were orders of magnitude below the lowest available endpoints for acute or chronic data, which buffered some of the concerns regarding the endpoint sensitivity.

The proposed new uses are likely to result in significant increases of broflanilide concentrations reaching aquatic systems, which may result in exceedances of the available chronic fish endpoints. However, EFED maintains the position that the available chronic toxicity study with the sheepshead minnow is sufficient for risk assessment purposes and can be relied upon for estimating potential risks to freshwater and estuarine/marine fish.

- **Guideline 850.1035**. The available mysid chronic toxicity study did not achieve a NOAEC and is classified as supplemental. The lack of a definitive NOAEC for the mysid is an uncertainty in the risk conclusions of the 2020 new chemical assessment. However, given the robust dataset for benthic invertebrates, the predominant sediment pathway of exposure, and the magnitude of the exceedance of the lowest test concentration in the mysid study by the exposure estimates, there is little doubt about the potential risks to aquatic invertebrates from the proposed uses. Therefore, while the guideline requirement remains to be fulfilled, the impact on the risk conclusions is considered low and submission of a new mysid chronic toxicity study is not needed. The available dataset for aquatic invertebrates is sufficient for risk assessment purposes.

As previously mentioned, four experimental studies (MRID 51780501-04) were submitted with this action. However, formal reviews of these studies were not completed at the time of writing. Preliminary reviews of these studies describe a lower (2-4 ton/A; MRID 51780501) poultry litter amendment rate and indicate that broflanilide degrades slowly (half-life = 453 days; MRID 51780502) and has limited bioavailability (MRIDs 51780503-04) in poultry litter. These findings are consistent with the behavior of broflanilide indicated in laboratory studies of other environmental media (*e.g.*, soil or sediment). No additional environmental fate data are needed for this assessment.

Table 1-1. Summary of Risk Quotients for Taxonomic Groups from Current Uses of Broflanilide

Taxa	Exposure Duration	Risk Quotient (RQ) Range[1]	RQ Exceeding the LOC for Non-listed Species	Additional Information/ Lines of Evidence
Freshwater Fish	Acute	<0.01-0.02	No	--
	Chronic	0.02-0.11	No	--
Estuarine/ Marine Fish	Acute	Not calculated	Not Applicable	Risk quotients (RQ) could not be calculated due to non-definitive endpoint. EECs are orders of magnitude below the highest tested concentration tested in the study which did not result in 50% or greater mortality indicating low acute risk to estuarine/marine fish.

Taxa	Exposure Duration	Risk Quotient (RQ) Range[1]	RQ Exceeding the LOC for Non-listed Species	Additional Information/ Lines of Evidence
	Chronic	0.08-0.15	No	--
Freshwater Invertebrates (Water-Column Exposure)	Acute	Not calculated	Not Applicable	RQs could not be calculated due to non-definitive endpoint. EECs are orders of magnitude below the highest tested concentration tested in the study which did not result in 50% or greater mortality indicating low acute risk to freshwater invertebrates in the water column.
	Chronic	0.15-0.92	No	--
Estuarine/ Marine Invertebrates (Water-Column Exposure)	Acute	**40-257**	**Yes**	RQs for poultry litter use exceed the acute level of concern (LOC) at field application rates of ≥0.02 lb a.i./A. RQs for poultry house perimeter treatment also exceeded the acute LOC.
	Chronic	**>479 - >3,039**	**Yes**	RQs exceed LOC for water-column species for all uses. NOAEC was not established in available study; so RQs were based on LOAEC of 0.0018 µg a.i./L, where there was 17% reduced survival for offspring and 22% reduced reproduction. No risks of concern to mollusks based on eastern oyster data.
Freshwater Invertebrates (Sediment Exposure)	Acute[2]	**452-2,877**	**Yes**	LOCs exceeded for all uses for single and multiple year modeling, for all freshwater benthic invertebrates.
	Chronic	**2,818-17,932**	**Yes**	LOCs exceeded for all uses for single and multiple year modeling, for all freshwater benthic invertebrates.
Estuarine/Marine Invertebrates (Sediment Exposure)	Acute[2]	**334-2,129**	**Yes**	LOCs exceeded for all uses for single and multiple year modeling, for all estuarine/marine benthic invertebrates.
	Chronic	**2,486-15,822**	**Yes**	LOCs exceeded for all uses for single and multiple year modeling, for all estuarine/marine benthic invertebrates. Non-definitive mysid endpoint because at the lowest test concentration, 0.0018 µg a.i./L, there was 17% reduced survival for F1 and 22% reduced offspring per female.
Mammals	Acute	Not calculated	Not Applicable	RQs not calculated due to non-definitive endpoint. There were no effects in the acute toxicity study. Risk is considered low for mammals.

Taxa	Exposure Duration	Risk Quotient (RQ) Range[1]	RQ Exceeding the LOC for Non-listed Species	Additional Information/ Lines of Evidence
	Chronic	Perimeter Spray <0.01-0.3 Poultry manure 0.01-0.50	No	Risk is considered low for mammals.
Birds	Acute	Not calculated	Not Applicable	RQs not calculated due to non-definitive endpoint. No effects in study.
	Chronic	Perimeter Spray 0.02-0.32 Poultry manure 0.06-**1.01**	No	The RQ of 1.01 exceeded the avian chronic LOC (1) for only birds feeding on short grass for manure applications. Although the RQ is exceeded for only birds feeding on short grass, this assessment concludes that chronic risk to birds is low considering that the highest modeled rate of 0.125 lbs a.i./A likely overestimates the application rate that is used on agricultural crops, and T-REX modeling likely overestimates potential contamination of diet food items on the field.
Terrestrial Invertebrates – Bees[3]	Acute Adult	Contact **5.5** Oral **39**	**Yes**	The proposed use of broflanilide as a poultry manure for field crops means that systemic transport would be required to achieve exposures to honeybees and is unlikely given the lack of support for systemic transport. For use as poultry house perimeter spray, risks were identified for honeybees and all non-target invertebrates that interact with soils for foraging diet, nesting, reproduction *etc*. These risks follow a single application and because of broflanilide' s persistence in soils, will likely increase with each annual application.
	Chronic Adult	**933**	**Yes**	
	Acute Larval	Not calculated	**Yes**	
	Chronic Larval	**3,059**	**Yes**	
Aquatic Plants	Vascular	Not calculated	Not Applicable	RQs could not be calculated due to non-definitive endpoint. EECs are orders of magnitude below the highest tested concentration tested in the study which did not result in 25% or greater inhibition indicating low risk to vascular plants.
	Non-vascular	<0.01-0.01	No	--

Taxa	Exposure Duration	Risk Quotient (RQ) Range[1]	RQ Exceeding the LOC for Non-listed Species	Additional Information/ Lines of Evidence
Terrestrial Plants	N/A	Not calculated	Not Applicable	RQs could not be calculated due to non-definitive endpoints (>0.091 lb a.i./A). The single max application rates for poultry house perimeter spray (0.018 lb a.i./A) and poultry manure field application (0.020, 0.040, and 0.080 lb a.i./A) are below the highest tested concentration in the available studies (0.091 lb a.i./A). Because the rates are below the concentrations that did not achieve a 25% effect level, risk is presumed low for terrestrial plants.

Level of Concern (LOC) Definitions:
Terrestrial Vertebrates: Acute=0.5; Chronic=1.0
Terrestrial Invertebrates: Acute=0.4; Chronic=1.0
Aquatic Animals: Acute=0.5; Chronic=1.0
Plants: 1.0
[1] RQs reflect exposure estimates for parent and maximum application rates allowed on labels.
[2] Based on water-column toxicity data compared to pore-water concentration.
[3] RQs for terrestrial invertebrates are applicable to honeybees, which are also a surrogate for other species of bees. Risks to other terrestrial invertebrates (*e.g.*, earthworms, beneficial arthropods) are only characterized when toxicity data are available.

2 Introduction

This S3NU ERA examines the potential ecological risks associated with labeled uses of broflanilide in and around poultry facilities on non-listed non-target organisms. Treviar™ SC (EPA Reg. # 7969-UON) is a soluble concentrate (SC) formulation used as a surface spray, spot, or Crack and Crevice® application used to control darkling beetles in and around poultry houses, proposed for registration by BASF, and submitted on behalf of Mitsui Chemicals Agro, Inc. (Mitsui). Label directions allow outdoor exterior applications as a perimeter treatment 18 inches up the wall and 6 inches out from the poultry house foundation. Within the poultry house, the label directions allow multiple applications to the surface of the litter. Because poultry litter is removed from the poultry house after the chicken growth cycle and potentially applied to fields as a means of disposal and fertilizer, it is necessary to determine the residues of broflanilide present when the litter is applied to agricultural fields. The amount of litter added to a field may vary, as it is a function of the nitrogen requirement of the crop receiving a litter application; therefore, to estimate the per acre rate of broflanilide residues being added to the field, multiple field application scenarios were modeled to characterize poultry litter application to agricultural fields.

Estimated field application rates of broflanilide residues ranged from 0.02 to 0.125 lb. a.i./A/year depending on the litter treatment rate applied to the field which varied from 2.0 to 12.5 tons/A (see **Appendix A** for calculations). Preliminary review of a submitted study (MRID

51780501) suggests a lower (2-4 ton/A) field application rate but there is still uncertainty to the actual amount the applicator will apply to the agricultural field. Corn was modeled as the representative crop in this assessment due to its higher nitrogen demand and the broflanilide usage as a pre-emergence application to corn.

3 Proposed Use Characterization

3.1 Mode of Action for Target Pests

Broflanilide is a diamide insecticide that has larvicidal activity against many chewing pests (wireworm, maggot, root worm, *etc.*). Nakao and Banba (2016) suggested that broflanilide is metabolized in insects to desmethyl-broflanilide, which acts as a noncompetitive resistant-to-dieldrin (RDL) γ-aminobutyric acid (GABA) receptor antagonist. The binding site of desmethyl-broflanilide was demonstrated to be distinct from that of conventional noncompetitive antagonist such as fipronil.

3.2 Label and Use Characterization

Broflanilide is proposed for registration for the control of darkling beetles in and around poultry houses, as listed in **Table 3-1.** Treviar™ SC (9.44% broflanilide; EPA Reg. # 7969-UON) is a soluble concentrate (SC) formulation applied as a surface spray, spot, or crack and crevice application. Proposed label instructions for indoor applications directs the applicator to apply the product in empty poultry houses to areas where beetle infestations occur such as walls, posts, floors, across the litter surface, and under feeder and water lines. Outdoor application instructions direct the applicator to make an exterior perimeter treatment 18 inches up the wall and 6 inches out from the foundation.

Table 3-1. Proposed Uses and Application Rates of Broflanilide In/Around Poultry Facilities

Uses	Formulation (% ai)	Annual Application Rate (lb a.i./A/YR)	Application Type	Comments
Indoor Applications[1]	Soluble Concentrate (SC; 9.44%)	0.71 (0.355 lb a.i./A x 2 applications)	Surface Spray, Spot, or Crack and Crevice® application	See **Appendix A** for calculations/ field adjustments
Outdoor Perimeter Treatment		0.14 (0.018 lb a.i./A x 8 applications)		

[1] Indoor applications subsequently become outdoor applications because poultry litter is removed from the poultry facility after the chicken growth cycle and potentially applied to agricultural fields as a means of disposal and fertilizer.

4 Residues of Concern

The Residues of Concern (ROC) for the aquatic exposure assessment include the parent compound (broflanilide) alone based on the low potential for aquatic exposure to each degradate as indicated by their presence and magnitude (as a percentage of the applied broflanilide) in the laboratory and field studies.

Major degradates ($\geq$10% of the applied parent) include DC-8007, AB-Oxa, S(Br-OH)-8007, MFBA benzoic acid, and carbon dioxide in some of the laboratory and field studies (**Appendix B**). Degradate DC-8007 is the only major, organic transformation product in environmentally relevant matrices, having formed in aerobic and anaerobic aquatic environments. Other major organic degradates (AB-Oxa, S(Br-OH)-8007, MFBA and benzoic acid) were identified in acidic and alkaline conditions of the aqueous photolysis study. These degradates may not be relevant under a neutral aquatic environment. As described below, broflanilide is stable to hydrolysis and soil photolysis and persists in soil and water bodies under aerobic and anaerobic conditions with half-lives of 157 to 5,700 days, demonstrating broflanilide' s environmental persistence and low degradate formation (**Appendix B**). In addition to their low exposure potential compared to broflanilide, aquatic and terrestrial animal toxicity data submitted to the agency show that tested major degradates are orders of magnitude less toxic than broflanilide.

5 Environmental Fate Summary

Physical and chemical properties for broflanilide are presented in **Table 5-1**. Broflanilide has a low solubility limit in water (0.71 mg/L at 20°C). Its vapor pressure of 2.4×10^{-11} torr and Henry's law Constant of 3.0×10^{-14} atm-m^3/mol (20°C) suggest volatilization is not a major dissipation pathway from dry or moist soils. Soil adsorption coefficient (K_F) values of 113 to 248 mL/g indicate low mobility in soil. The mean K_F values of 48 L/kg for DM-8007 and 17 L/kg for DC-DM-8007 **(Table 5-2)** suggest that the degradates are more mobile than broflanilide. The coefficients of variation suggest that K_F values are a better descriptor of broflanilide sorption to soil than K_{FOC} **(Table 5.1)**. The Log Kow of 5.2 at pH 4 and 7 suggests broflanilide has the potential for bioaccumulation. The bioconcentration factors in rainbow trout whole fish tissues are 266-364X. If contaminated fish reach uncontaminated water, depuration half-lives are less than 3 days in all fish matrices, with >95% of the total residues accumulated during 28 days of exposure eliminated in 10 days (MRID 50211451). The degradate (DM-8007) of broflanilide was observed in the edible and non-edible tissues in the BCF study indicating that metabolism may be contributing to the depuration rate in the BCF study. However, no radioactivity was detected in the tank water during the depuration phase.

Table 5-1. Summary of Physical-Chemical, Sorption, and Bioconcentration Properties of Broflanilide

<table>
<tr><th>Parameter</th><th colspan="5">Value[A]</th><th>Source/ Study Classification/ Comment</th></tr>
<tr><td>Molecular Weight (g/mol)</td><td colspan="5">663.29</td><td rowspan="4">MRID 50211316</td></tr>
<tr><td>Water Solubility at 20°C (mg/L)</td><td colspan="5">0.71</td></tr>
<tr><td>Vapor Pressure (torr)</td><td colspan="5">2.4×10^{-11} (20°C)
6.6×10^{-11} (25°C)</td></tr>
<tr><td>Henry's Law constant at 20°C (atm-m^3/mol)</td><td colspan="5">3.0×10^{-11}
(3.0×10^{-6} Pa-m^3/mol)</td></tr>
<tr><td>Log Dissociation Constant (pKa)</td><td colspan="5">8.8</td><td>MRID 50211316
Expected to partially ionize under alkaline pH</td></tr>
<tr><td>Octanol-water partition coefficient (K_{ow}) at 25°C (unitless)</td><td colspan="5">5.2 @ pH 4 and 7
4.4 @ pH 10</td><td>MRID 50211316</td></tr>
<tr><td>Air-water Partition Coefficient (log K_{AW}) (unitless)</td><td colspan="5">log K_{AW} = -6.44</td><td>EPIWEB 4.1 (estimated value)[C].
non-volatile from water</td></tr>
<tr><td rowspan="10">Freundlich Soil-Water Distribution Coefficients (K_F in L/kg-soil or sediment)

Organic carbon normalized Freundlich distribution coefficients (K_{Foc} in L/kg-organic carbon)</td><td>Soil/Sediment</td><td>K_F</td><td>K_{FOC}</td><td colspan="2">1/N</td><td rowspan="10">MRID 50211432
Acceptable.
Slightly to Hardly Mobile (FAO classification system);
K_F better predictor of sorption based on lower CV.</td></tr>
<tr><td>ND Loam</td><td>246</td><td>6474</td><td colspan="2">1.0</td></tr>
<tr><td>CA sandy loam</td><td>113</td><td>20204</td><td colspan="2">0.99</td></tr>
<tr><td>NB loam</td><td>116</td><td>5797</td><td colspan="2">0.92</td></tr>
<tr><td>UK silt loam</td><td>181</td><td>4643</td><td colspan="2">0.90</td></tr>
<tr><td>ND loam</td><td>248</td><td>3596</td><td colspan="2">0.93</td></tr>
<tr><td>Goose River Sediment</td><td>158</td><td>4924</td><td colspan="2">0.86</td></tr>
<tr><td>Mean</td><td>177</td><td>7606</td><td colspan="2">--</td></tr>
<tr><td>CV[B]</td><td>0.34</td><td>0.82</td><td colspan="2">--</td></tr>
<tr><td>Japan Sandy[D] loam</td><td>89</td><td>2952</td><td colspan="2">0.98</td></tr>
<tr><td rowspan="5">Steady State Bioconcentration Factor (BCF) L/kg-wet weight fish or L/kg wet weight lipid</td><td rowspan="2">Species</td><td rowspan="2" colspan="2">BCF</td><td colspan="2">Depuration Half-Lives (d)</td><td rowspan="5">MRID 50211562
Acceptable.

>95% elimination of residues in 10 days</td></tr>
<tr><td>1.0 µg/L</td><td>10 µg/L</td></tr>
<tr><td rowspan="3">Rainbow trout (Oncorhynchus mykiss)</td><td colspan="2">Whole fish
266-364X</td><td>2.2</td><td>1.5</td></tr>
<tr><td colspan="2">Edible
175-240X</td><td>2.6</td><td>1.5</td></tr>
<tr><td colspan="2">Nonedible
344-468X</td><td>2.2</td><td>1.5</td></tr>
</table>

Parameter	Value[A]	Source/ Study Classification/ Comment
[A] All estimated values were calculated according to "*Guidance for Reporting on the Environmental Fate and Transport of the Stressors of Concern in Problem Formulations for Registration Review, Registration Review Risk Assessments, Listed Species Litigation Assessments, New Chemical Risk Assessments, and Other Relevant Risk Assessments*" (USEPA, 2010). [B] CV=Coefficient of Variation [D] Due to the volcanic parent material of the Japanese soil that is not comparable to most US soils, these K_F and K_{FOC} values were not included to calculate mean and CV values. -- = Not Applicable		

Table 5-2. Summary of Soil Sorption Coefficients of Broflanilide Degradates

Parameter	Soil/Sediment	Degradates						Source/ Study Classification/ Comment
		DC-8007			DC-DM-8007			
		K_F	K_{FOC}	1/N	K_F	K_{FOC}	1/N	
Soil adsorption coefficients K_F and K_{FOC} (L/kg)	ND loam	85	1984	1.10	29	681	0.91	MRIDs 50211433 & 50211434 Acceptable.
	NB loam	31	1496	0.97	14	668	0.94	
	TX sand	15	5097	0.96	4	1489	0.99	
	TX clay loam	72	2333	1.03	22	707	0.88	
	CA sandy loam	36	4504	0.99	14	1746	0.81	
Mean	All soils	48	3083	--	17	1058	--	
CV	All soils	0.62	0.52	--	0.57	0.49	--	
-- = Not applicable								

The environmental fate properties of broflanilide are listed in **Table 5-3**. Broflanilide is stable to hydrolysis and soil photolysis and persists in soil and water bodies under aerobic and anaerobic conditions with half-lives of 157 to 5,700 days. Aqueous photolysis may be the main route of degradation, and is pH dependent, with half-lives of 18 days at pH 5, 80 days at pH 7, and 4 days at pH 9. The major photodegradation products at pH 5 were S(Br-OH)-8007 (up to 14% of the applied), MFBA (up to 20% of the applied), and benzoic acid (up to 26% of the applied). At pH 9, the major photodegradation products were MFBA (up to 26% AR), benzoic acid (up to 44% of AR), and AB-oxa (up to 38% of AR). There were no major photodegradation products at pH 7. Several minor degradates (S(PFP-OH)-8007, S(F-OH)-8007, and DBr-8007) were also identified in the aqueous photolysis study. Photodegradation in basic or acidic aquatic environments could be a more important route of degradation as compared to photolysis in neutral conditions.

Table 5-3. Summary of Environmental Fate Properties of Broflanilide

Study	System Details	Half-life (days)[A,B]	Classification/Comment
Abiotic Hydrolysis	pH 5, 7, and 9, 50°C	Stable	MRID 50211328, Acceptable

Study	System Details	Half-life (days)[A,B]	Classification/Comment
Aqueous Photolysis	pH 7, 20°C 40°N sunlight	80 (SFO) @ pH 7	MRID 50211329, Acceptable
	pH 5 and 9, 20°C 40°N sunlight	18 (SFO) @ pH 5 4 (SFO) @ pH 9	MRID 50211330, Acceptable
Soil Photolysis	IL Silt Loam, 20°C, pH 5.9 40°N sunlight	Stable	MRID 50211429, Acceptable.
Photolysis in Air	Hydroxyl Radicals Reaction (1.5 $\times 10^{-6}$ OH/cm^3)	2.5	EPIWEB 4.1 (estimated value)[C]. non-volatile from water
Aerobic Soil Metabolism	CA Centerville Clay, 20°C	1173 (SFO) (*829 @ 25°C*)[C]	MRID 50211427, Acceptable.
	IL Drummer Silty clay loam, 25°C	2220 (SFO)	MRID 50211430, Acceptable. Reported half-lives were based on 365 days sampling data.
	NC Norfolk sandy loam 25°C	1485 (SFO)	
	TN Falaya Silt loam, 25°C	2135 (SFO)	
Anaerobic Soil Metabolism	CA Centerville Clay, 20°C	1117 (SFO)	MRID 50211430, Acceptable.
	IL Drummer Silty clay loam, 20°C	157 (SFO)	
	NC Norfolk sandy loam 20°C	2354 (SFO)	
	TN Falaya Silt loam, 20°C	1113 (SFO)	
Aerobic Aquatic Metabolism	Brandywine Creek Sediment from PA, 20°C	1430 (DFOP)	MRID 50211437, Acceptable
	Choptank River Sediment from MD, 20°C	945 (SFO)	
Anaerobic Aquatic Metabolism	Brandywine Creek Sediment from PA, 20°C	871 (SFO)	MRID 50211438, Acceptable
	Choptank River Sediment from MD, 20°C	1411 (SFO)	

[A] The value used to estimate a model input value is the calculated SFO DT_{50}, T_{IORE}, or the DFOP slow DT_{50} from the DFOP equation. The model chosen is consistent with that recommended using the, *Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media* (NAFTA, 2012).
[B] SFO=single first order; DFOP=double first order in parallel; IORE=indeterminate order (IORE); SFO DT_{50}=single first order half-life; T_{IORE}=the half-life of a SFO model that passes through a hypothetical DT_{90} of the IORE fit; DFOP slow DT_{50}=slow rate half-life of the DFOP fit.
[C] Since all the reported DT_{50} values were based on 20°C for aerobic soil metabolism except for this soil, the reported half-life value was adjusted to 25°C based on a Q_{10} of 2.0.

Broflanilide persists in terrestrial and aquatic environments. In aerobic soil, the DT_{50} values of broflanilide were calculated to be 829, 1485, 2135 and 2220 days for CA, NC, TN and IL soils, respectively. There were no major (>10% of applied radioactivity (AR)) degradation products but several minor transformation products were detected in soil. Very little mineralization in soil was observed with levels of CO_2 reaching a maximum of 1.2% AR after 365 days of incubation. The estimated half-life values of broflanilide in anaerobic soil were 157, 1113, 1117 and 2354 days for IL, TN, CA and NC soils, respectively, indicating that broflanilide is persistent in soil under both aerobic and anaerobic conditions. There was only one major transformation product observed, DC-8007, at a maximum amount of 74% AR in the anaerobic soil metabolism study. Several minor degradates (S(PFP-OH)-8007, DM-8007, and DC-DM-8007) were identified in soil/sediment metabolism studies. Percent formation of transformation products from broflanilide studies is provided in **Table B-1 (Appendix B)**.

Broflanilide is also persistent (DT_{50} values of 945 and 1430 days) under stratified redox test conditions in sediment samples from Choptank River, MD and Brandywine Creek, PA under aerobic aquatic conditions. Similar DT_{50} values of 871 to 1411 days were observed under anaerobic aquatic conditions. The only major transformation product under both aerobic and anaerobic aquatic conditions was DC-8007, detected at 12% to 18% in a Brandywine Creek sediment.

Several other unidentified minor transformation products (Unidentified Extracted Residues [UER]) in **Table B-1 (Appendix B)** were detected at maximum individual concentrations of <10% of AR in various environmental fate studies; however, the maximum total concentrations of unidentified transformation products reached very high levels of 45% AR at pH 5 and 65% AR at pH 9 in the aqueous photolysis study.

Unextracted residues (UR) accounted for 5% to 14% of the applied in the environmental fate metabolism studies. Soil samples with high amounts of URs from an aerobic soil metabolism study (MRID 50211427) were used to determine the residue extractability using methanol:water (high dielectric constant), followed by ethyl acetate (polar with low dielectric constant), then hexane (non-polar) and lastly dioxane (non-polar) as extraction solvents. The extraction procedure with multiple solvents of different dielectric constants did not significantly reduce the amounts of URs. The additional solvents did not extract more than 1.4% of the applied (<LOQ to 1.4% of applied was extracted), which indicates that the majority of URs were strongly bound with the soil or sediment.

Terrestrial field dissipation (TFD) of broflanilide was studied using bare ground plots at five sites in the U.S.A., including sites in North Carolina, Florida, California, Washington, and North Dakota. A summary of TFD data is provided in **Table 5-4**. Dissipation half-lives ranged from 13 to 188 days across the five sites in the United States. Based on the results observed in the TFD studies, broflanilide dissipated in all locations with the formation of low levels of degradates [DM-8007, S(PFP-OH)-8007, DC-DM-8007 and DC-8007]. None of the residues appeared inherently prone to leaching and remained almost exclusively in the topsoil (0-6 inches), which is consistent with the relatively high soil adsorption coefficients of broflanilide and its degradates.

Overall, these terrestrial field dissipation results indicate that compound persistence is highly dependent on the environmental conditions. While most residues in terrestrial field dissipation studies remained in the top-soil layer, residues were detected in the lowest depth of 6 inches (15 cm) sampled. This indicates that broflanilide has low potential to leach to groundwater in most but not all environments. While field dissipation studies are designed to capture a range of loss processes; laboratory studies are designed to capture loss from one process (*e.g.*, hydrolysis or aerobic metabolism). In addition, a non-guideline outdoor aerobic soil metabolism study (MRID 50211560) was conducted on bare soil under field conditions at two sites in

California and Georgia. Most of the applied material and resulting degradation products were confined to the uppermost 0-5 cm horizon throughout the study resulting in no significant losses via leaching to lower depths. Dissipation/degradation half-lives values ranged from 57 days for California site and 182 days for Georgia site, are similar to TFD half-lives. Thus, the degradation half-lives from the laboratory studies (DT_{50}s of 829 to 2220 days) are not directly comparable to the dissipation half-lives from the field studies (38 to 188 days); however, it is informative to have some understanding of how the laboratory data compares to the loss rates in the field dissipation studies.

Table 5-4. Summary of Field Dissipation Data for Broflanilide

Study	System Details	Broflanilide Half-life (days)[1,2]	Max Leaching Soil Core Depth (cm)	Source, Classification
Terrestrial Field Dissipation (DT_{50})	Southern Coastal Plain, NC	38 (IORE)	0-15	MRID 50211431, Acceptable
	Southern Florida Flatwoods, FL	57 (IORE)	0-15	
	Sacramento and San Joaquin Valleys, CA	118 (IORE)	0-15	
	Columbia Basin, WA	13 (IORE)	0-15	
	Red River Valley of the North, ND	188 (IORE)	0-15	

[1] The value used to estimate a half-life value is the calculated SFO DT_{50}, T_{IORE}, or the DFOP slow DT_{50} from the DFOP equation. The model chosen is consistent with that recommended using the *Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media* (NAFTA, 2012).
[2] IORE=indeterminate order (IORE); T_{IORE}=the half-life of a SFO model that passes through a hypothetical DT_{90} of the IORE fit.

6 Ecotoxicity Summary

Ecotoxicity data for broflanilide and its associated degradates (including DC-DM-8007, DC-8007, DM-8007, AB-Oxa, S(Br-OH)-8007, and MFBA) are available; however, because the aquatic and terrestrial toxicity data for the degradates indicate that they are orders of magnitude less toxic than broflanilide, their data are not discussed in this assessment (see USEPA 2020 for details). The most sensitive endpoints from the data package are summarized in **Section 6.1** and **Section 6.2**.

Table 6-1 and **Table 6-2** summarize the most sensitive measured toxicity endpoints available across taxa. These endpoints may not capture the most sensitive toxicity endpoint for a particular taxon but capture the most sensitive endpoint across tested species for each taxon for which data were submitted. All studies in this table are classified as acceptable or supplemental. Non-definitive endpoints are designated with a greater than (>) or less than (<) value.

6.1 Aquatic Toxicity

Table 6-1 summarizes the most sensitive toxicity endpoints for aquatic organisms.

Fish

Several acute freshwater fish studies were submitted to the agency. The most sensitive of these was a test on the bluegill (*Lepomis macrochirus*) which resulted in an LC_{50} of 251 µg a.i./L. There was a steep dose response with 3% mortality at 158 µg a.i./L and 100% mortality at 290 µg a.i./L, contributing to uncertainty in the estimated LC_{50}. Similarly, in a study with rainbow trout (*Oncorhynchus mykiss*), the LC_{50}= 359 µg a.i./L with a steep dose response (<260 µg a.i./L no mortality, and doses 260 µg a.i./L with 15% and 649 µg a.i./L with 100% mortality). These responses contribute to the uncertainty in the estimated acute endpoints for these studies. The other two studies testing fathead minnow (*Pimphales promelas*) and Carp (*Cyprinus carpio*) each had few mortalities at their highest tested concentrations so estimated LC_{50}s were non-definitive (>508 and >498 µg a.i./L respectively). The only estuarine marine acute fish study, tested sheepshead minnow (*Cyprinodon variegatus*) also had 10% mortality and an LC_{50}> 1300 µg a.i./L.

Two early life-stage chronic fish toxicity studies testing the sensitivity of fathead minnow (*Pimphales promelas*) and sheepshead minnow (*Cyprinodon variegatus*) were submitted. In the fathead minnow study, there were statistically significant 9% and 85% reductions in larval survival at 147 and 475 µg a.i./L. respectively; therefore, the NOAEC was established at 51 µg a.i./L. The 475 µg a.i./L test concentration also showed significant effects to weight (68 - 72 % reduction) and length (33% reduction). Given the apparent difference in sensitivity among fish test species, it is unknown if bluegill or rainbow trout would result in more sensitive endpoints that those provided in the fathead minnow test. Typically, an acute to chronic ratio would be used to estimate the NOAECs for these taxa, however in this case the acute fathead minnow study did not result in a definitive $LC_{50}$and had little mortality. So, this remains an uncertainty for freshwater fish. In the sheepshead minnow study, the NOAEC was established at 11 µg a.i./L., based on reduced length (4%), dry weight (10-13%), wet weight (10%), and time to hatch (16%) at 25.2 µg a.i./L. Additionally, significant reduction in survival (91%) was observed at 159 µg a.i./L.

Water Column Invertebrates

Acute freshwater invertebrate data testing daphnia (Daphnia magna) showed no effects up to the highest tested concentration, 322 µg a.i./L, therefore the LC_{50} is >322 µg a.i./L. Acute studies on the eastern oyster (*Crassostrea virginica*) and mysid (*Americamysis bahia*) were also submitted. The oyster study showed no effects up to the highest tested concentration (LC_{50} > 440 µg a.i./L). The mysid was sensitive to broflanilide under the conditions of the test, with an LC_{50} of 0.0215 µg a.i./L. There was a steep dose response with 35%, 95% and 100% mortality at 0.0202, 0.0284, and 0.0428 µg a.i./L respectively. Mysids in the 0.0107 µg a.i./L test concentration showed no signs of chemical stress.

Chronic Daphnia and mysid toxicity studies showed sensitivity to broflanilide. The available Daphnia study resulted in a NOAEC of 5.93 µg a.i./L based upon 6-8% reductions in length, total offspring, birth rate, and time to first brood at 11.6 µg a.i./L. The submitted mysid chronic toxicity study did not establish a definitive NOAEC endpoint because at the lowest test concentration, 0.0018 µg a.i./L, there was 17% reduced survival for F1 and 22% reduced offspring per female.

Benthic Invertebrates

Three sub-chronic (10-day) toxicity studies on benthic invertebrates were submitted. In a static renewal sediment test with *Chironomus dilutus* the $LC_{50}$was 9.99 µg ai/kg-dry sediment (0.211 µg ai/L pore water, 454 µg ai/kg-OC (organic carbon normalized sediment)) based on mean-measured concentrations. The NOAEC for survival was 1.5 µg/kg dry sediment (0.032 µg/L pore water, 68 µg ai/kg OC) based on 9% reduction in survival at the LOAEC (4.8 µg/kg dry sediment). In a static renewal sediment test with *Hyalella azteca* the $LC_{50}$was 13.5 µg ai/kg-dry sediment (0.461 µg ai/L pore water, 752 µg ai/kg OC) based on mean measured concentrations. The NOAEC for survival was 4.9 µg ai/kg-dry sediment (0.16 µg ai/L pore water, 270 µg ai/kg OC) based on 12% reduced survival at the LOAEC (9.5 µg ai/kg-dry sediment). In a study testing the estuarine/marine invertebrate *Leptocheirus plumulosus*, the $LC_{50}$was determined as 14 µg ai/kg-dry sediment (0.079 µg ai/L pore water1, 410 µg ai/kg-organic carbon) based on mean-measured concentrations. The NOAEC for survival was 9.6 µg ai/kg-dry sediment (0.054 µg ai/L pore water, 0.29 µg ai/kg OC) based on 100% reduced survival at the LOAEC (20 µg ai/kg-dry sediment).

Three chronic toxicity studies on benthic invertebrates were also submitted. In a 60-day static-renewal sediment test with *Chironomus dilutus*, the overall NOAEC was 1.5 µg ai/kg-dry sediment (0.024 µg ai/L pore water; 67 µg ai/kg OC) based on 20% reduced survival and 36% reduced percent emergence. No other endpoints were significantly affected by exposure to the test material. There was significant solvent interference in the study which was considered when selecting the NOAEC from among the responses for these endpoints. In a 42-day reproduction study on *Hyalella azteca,* significant solvent effects were observed for several endpoints, confounding the interpretation of the chemical response. This was considered when determining the NOAECs and LOAECs for the measured endpoints. The overall NOAEC was non-definitive (< 1.7 µg ai/kg-dry sediment; <0.039 µg ai/L pore water; < 91 µg ai/kg OC) based on a 46% reduction in male to female ratio. NOAECs were also determined for survival (6.7 µg ai/kg-dry sediment; >20% reductions) and reproduction (3.3 µg ai/kg-dry sediment; >45% reductions). In a 28-day spiked sediment test with *Leptocheirus plumulosus*, the NOAEC was determined to be 3.8 µg ai/kg-dry sediment (0.021 µg ai/L pore water; 130 µg ai/kg OC) based on 12% reduced survival at the LOAEC (8.4 µg a.i./kg dry sediment). No effects to growth or reproduction were observed.

Aquatic Plants

The most sensitive aquatic non-vascular plant toxicity study with technical grade broflanilide was a static toxicity study (MRID 50211458) with *Skeletonema costatum*, in which there were significant ($p<0.05$) reductions in cell density. The 96-hour IC_{50} was 570 µg a.i./L and the NOAEC was 160 µg a.i./L. No other tested species showed effects.

In a static toxicity study of broflanilide (MRID 50211464) with the freshwater vascular plant duckweed (*Lemna gibba*), there were no observed chemical effects (IC_{50}> 630 µg a.i./L; NOAEC > 630 µg a.i./L).

Table 6-1. Aquatic Toxicity Endpoints Selected for Risk Estimation for Broflanilide

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value in µg a.i./L (unless otherwise specified)	MRID or ECOTOX No./ Classification	Comments
Freshwater Fish (Surrogates for Vertebrates)					
Acute	TGAI (99)	Bluegill *Lepomis macrochirus*	96-h LC_{50} = 251	50211452 Acceptable	Static renewal test Since the dose response is so steep, there is uncertainty in the estimated LC_{50}; the true LC_{50} falls above 158 µg a.i./L (3% mortality) and below 290 µg a.i./L (100% mortality).
Chronic	TGAI (99)	Fathead Minnow *Pimphales promelas*	34-Day NOAEC = 51 LOAEC = 147	50211449 Acceptable	Based on reduced larval survival (9%) at LOAEC
Estuarine/Marine Fish (Surrogates for Vertebrates)					
Acute	TGAI (99)	Sheepshead Minnow *Cyprinodon variegatus*	96-h LC_{50} = >1300	50211490 Acceptable	10% mortality at 1300 µg a.i./L
Chronic	TGAI (99)	Sheepshead Minnow *Cyprinodon variegatus*	34-Day NOAEC = 11 LOAEC = 25	50211450 Acceptable	Based on reduced length (4%), dry weight (10-13%), wet weight (10%), time to hatch (16%).
Freshwater Invertebrates (Water-Column Exposure)					
Acute	TGAI (99)	Water Flea *Daphnia magna*	48-h LC_{50} > 322	50211452 Acceptable	No effects at highest test concentration
Chronic	TGAI (99)	Water Flea *Daphnia magna*	21-Day NOAEC = 5.93 LOAEC = 11.6	50211566 Acceptable	LOAEC based on 6-8% reductions in length, total offspring, birth rate, and time to first brood

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value in µg a.i./L (unless otherwise specified)	MRID or ECOTOX No./ Classification	Comments
1.0 µg/L					
Acute	TGAI (99)	Mysid *Americamysis bahia*	96-h LC_{50} = 0.0215	50211485 Acceptable	None
Chronic	TGAI (99)	Mysid *Americamysis bahia*	28-Day NOAEC < 0.0018 LOAEC = 0.0018	50211488 Supplemental	LOAEC based on F1 survival 18% reduced survival and 22% less offspring per female. Classification based on lack of a definitive NOAEC.
Freshwater Invertebrate (Sediment Exposure)					
Sub-chronic	TGAI (99)	Midge *Chironomus dilutus*	10-day <u>Sediment:</u> NOAEC = 1.5 LOAEC = 4.8 µg/kg-dry Sediment <u>Pore-water:</u> NOAEC = 0.032 LOAEC = 0.098 µg a.i./L	50211459 Acceptable	Based on 9% reduction in survival at the LOAEC (4.8 µg/kg-dry sediment). LC_{50} = 9.99 µg a.i./kg dry sediment LC_{50} = 454 µg a.i./kg- OC LC_{50}= 0.211 µg a.i./L-pore water
Sub-chronic	TGAI (99)	Amphipod *Hyalella azteca*	10-day <u>Sediment:</u> NOAEC = 4.9 LOAEC = 9.5 µg a.i./kg-dry sediment <u>Pore-water:</u> NOAEC = 0.16 LOAEC = 0.30 µg a.i./L	50211460 Acceptable	Based on 12% reduced survival at the LOAEC (9.5 µg a.i./kg-dry sediment). LC_{50} = 13.5 µg a.i./kg dry sediment LC_{50} = 752 µg a.i./kg OC LC_{50} = 0.461 µg a.i./L pore water
Chronic	TGAI (99)	Midge *Chironomus dilutus*	60-day NOAEC = 1.5 LOAEC = 4.7 µg a.i./kg-dry sediment NOAEC = 67 LOAEC = 213 µg a.i./kg OC NOAEC = 0.024 LOAEC = 0.079 µg a.i./L pore water	50211461 Acceptable	LOAEC Based on 36% reduction in percent emergence and 20% reduction in survival.

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value in µg a.i./L (unless otherwise specified)	MRID or ECOTOX No./ Classification	Comments
Chronic	TGAI (99)	Amphipod *Hyalella azteca*	42-day NOAEC < 1.7 LOAEC = 1.7 µg a.i./kg dry sediment NOAEC < 91 LOAEC = 91 µg a.i./kg OC NOAEC < 0.039 LOAEC = 0.039 µg a.i./L pore water	50211462 Supplemental	Significant solvent effects were observed for several endpoints, confounding the interpretation of the chemical response. LOAEC based on 46% reduction in male to female ratio. Other NOAECs: Survival = 6.7 µg a.i./kg-dry sediment (>20% reductions) Reproduction & Number of Offspring/female = 3.3 µg a.i./kg-dry sediment (>45% reductions)
Estuarine/ Marine Invertebrates (Sediment Exposure)					
Sub-chronic	TGAI (99)	Amphipod *Leptocheirus plumulosus*	10-day <u>Sediment:</u> NOAEC = 9.6 µg a.i./kg-dry sediment LOAEC = 20 µg a.i./kg-dry sediment <u>Pore water:</u> NOAEC = 0.054 µg a.i./L pore water	50211487 Acceptable	based on 100% reduced survival at the LOAEC LC_{50} = 14 µg a.i./kg dry sediment LC_{50} = 410 µg a.i./kg-OC LC_{50} = 0.079 µg a.i./L pore water
Chronic	TGAI (99)	Amphipod *Leptocheirus plumulosus*	28-day NOAEC = 3.8 LOAEC = 8.4 µg a.i./kg-dry sediment NOAEC = 130 LOAEC = 290 µg a.i./kg OC NOAEC = 0.021 LOAEC = 0.048 µg a.i./L pore water	50211463 Acceptable	Overlying water spiked (refreshed 12 times day) Estimated pore water concentrations. LOAEC Based on 36% reduction in percent emergence and 12% reduction in survival.
Aquatic Plants and Algae					
Vascular	TGAI (99)	Duckweed *Lemna gibba*	EC_{50} > 630 NOAEC = 630	50211464 Acceptable	No effects
Non-vascular	TGAI (99)	Marine Diatom *Skeletonema costatum*	9-d EC_{50} = 570 NOAEC = 160	50211458 Acceptable	Cell density

TGAI=Technical Grade Active Ingredient; TEP= Typical end-use product; a.i.=active ingredient

>Greater than values designate non-definitive endpoints where no effects were observed at the highest level tested, or effects did not reach 50% at the highest concentration tested (USEPA, 2011).
< Less than values designate non-definitive endpoints where growth, reproductive, and/or mortality effects are observed at the lowest tested concentration.

6.2 Terrestrial Toxicity

Table 6-2 contains a summary of the most sensitive toxicity values for terrestrial organisms.

Birds

An acute oral toxicity test of TGAI with bobwhite quail (*Colinus virginianus*; MRID 50211439), mallard duck (*Anas platyrhynchos*; MRID 50211440), and canary (*Serinus canaria*; MRID 50211441) reported no effects in response broflanilide at 2000 mg a.i./kg-bw. Based on these data, broflanilide is classified as practically non-toxic to birds on an acute oral exposure basis.

No mortalities or sublethal effects were observed in subacute dietary toxicity studies with bobwhite quail (*Colinus virginianus*; MRID 5021143) or mallard duck (*Anas platyrhynchos*; MRID 50211442). The LC_{50}s are >5000 mg a.i./kg-diet. Based on these data, broflanilide is classified as practically non-toxic to birds on a subacute dietary exposure basis.

In an avian reproduction study with mallard ducks (MRID 50211561), growth and reproductive effects (reduced eggs laid and 14% reduction in surviving hatchlings) were observed at 87.4 mg a.i./kg-diet (NOAEC = 29.7 mg a.i./kg-diet). At the 276 mg a.i./kg-diet test concentration, there were slight reductions in egg production that were considered to have been related to treatment. Additionally, there were slight (5-6%), but significant dose-dependent reductions from control on survivor weights at the 87.4 and 276 mg a.i./kg-diet treatment levels. There were no other treatment-related effects observed. A reproduction study with bobwhite quail (MRID 50211445) showed significant inhibitions in 14-days survivors/hatchling at the mean-measured 506 and 1021 mg a.i./kg-diet treatment groups, and in 14-day survivor weight at the mean-measured 1021 mg a.i./kg-diet (NOAEC = 254 mg a.i./kg-diet).

Mammals

An acute oral toxicity study with rats (*Rattus norvegicus*; MRID 50211349) reported no chemical related effects at the highest tested concentration (LC_{50} > 5000 mg a.i./kg-bw). Therefore, broflanilide is considered practically non-toxic to mammals on an acute oral exposure basis.

In a two-generation reproduction study (MRID 49575319) with rats (*R. norvegicus*), there were no observed effects related to growth or survival of adults, however decreased pup weights were observed in both male and female F1 pups (5-7%) and this increased in F2 pups (6-10%) at 1500 and 15000 ppm. The study NOAEC based on the pup weight effects is 300 mg a.i./kg-diet (26 mg a.i./kg-bw/day).

Terrestrial Invertebrates (Bees)

Broflanilide is highly toxic to honey bees and bumble bees on both an acute contact and oral exposure basis. In an acute (single dose) contact and acute oral combined toxicity study with adult honey bees (*Apis mellifera*; MRID 50211466), technical grade active ingredient (≥ 98% a.i.) was used. The study provided the most sensitive 48-hr contact LD50 = 0.0088 µg a.i./bee as well as the most sensitive acute oral LC_{50}= 0.0149 µg a.i./bee. Two additional acute oral and acute contact toxicity studies on adult honey bees with TGAI (98% a.i.; MRID 50124717) and TEP (9.6% a.i.; MRID 50325607) were submitted. Acute contact LC_{50}s estimated from these studies ranged from 0.012 to 0.017 µg a.i./bee and acute oral LC_{50}s ranging from 0.045 to 0.0693 µg a.i./bee (details in **Appendix D**). Additional broflanilide toxicity studies were conducted using TGAI (98% a.i.; MRID 50211466) and TEP (9.6% a.i.; MRID 50325608) with the social non-*Apis* bumblebee *Bombus terrestris*. In the contact toxicity tests, the 48-hr LC_{50}s were >0.120 and 0.122 µg a.i./bee respectively. These studies also tested the acute oral toxicity of the compounds with bumblebees; 48-hour acute oral LC_{50}s were 0.0195 and 0.0139 µg a.i./bee respectively. An acute (1-day) exposure toxicity test with larval honey bees conducted with TGAI (98% a.i.; MRID 50211471) was submitted. This resulted in an 8-day LC_{50} of >0.029 µg a.i./larva/day. Significant mortality (36%) was observed at the highest tested concentration 0.029 µg a.i./larva/day. Based on these results, broflanilide is considered highly toxic to adult and larval bees.

A 10-day chronic (repeat dose) toxicity test with adult honeybees (MRID 50211469) conducted with broflanilide technical (98% a.i.) resulted in NOAEL of 0.00062 µg a.i./bee/day and LOAEL of 0.0011 µg a.i./bee/day based on 30% mortality. Surviving bees at the LOAEL were reported to show uncoordinated movements. The next two doses 0.00237 and 0.0049 µg a.i./bee/day resulted in 93 and 100% mortality.

A 22-day chronic (repeat dose) toxicity test with larval honeybees (MRID 50211472) conducted with TGAI (98% a.i.) resulted in a NOAEL of 0.000080 µg a.i./larva/day based on 18% larval mortality at 0.00027 µg a.i./larva/day. This result was not statistically significant; however mortality followed a dose response and this level of response was considered to be biologically significant. Pupal mortality and percent emergence were also significantly affected by exposure with NOAELs of 0.0008 µg a.i./larva/day.

Terrestrial Plants

Submitted terrestrial plant seedling emergence (MRID 50325617) and vegetative vigor (MRID 50325616) studies were conducted on *Allium cepa* (onion), *Lolium perenne* (ryegrass), *Triticum aestivum* (wheat), *Zea mays* (corn), *Beta vulgaris* (sugar beet), *Brassica napus* (rape), *Brassica oleracea* (cabbage), *Glycine max* (soybean), *Lactuca sativa* (lettuce), and *Lycopersicon esculentum* (tomato) with a TEP (9.6% a.i.). In the vegetative vigor study, the most sensitive dicots were sugar beet (NOAEC < 0.0023 lb a.i./A) and cabbage (NOAEC = 0.014 lb a.i./A); however, the observations did not manifest in a dose response manner and regression-based toxicity endpoints (IC_{25}s) were highly uncertain. No other plants tested in the vegetative vigor or seedling emergence studies responded to the formulations; therefore, the IC_{25}s for monocots and dicots for both studies were determined to be >0.091 lbs a.i./A.

Table 6-2. Terrestrial Toxicity Endpoints Selected for Risk Estimation for Broflanilide.

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value[1]	MRID or ECOTOX No./ Classification	Comments
Birds (Surrogates for Terrestrial Amphibians and Reptiles)					
Acute Oral	TGAI (98.67)	Mallard duck (*Anas platyrhynchos*)	LD_{50} > 2000 mg a.i./kg-bw	50211440 (Acceptable)	Practically Non-Toxic No effects
Sub-acute dietary	TGAI (98.6)	Mallard duck (*Anas platyrhynchos*)	LC50 > 5000 mg a.i./kg-diet LD50 > 1364 mg a.i./kg-bw	50211443 (Acceptable)	Practically non-toxic. No effects
Chronic	TGAI (98.67)	Mallard duck (*Anas platyrhynchos*)	NOAEC = 29.7 mg LOAEC = 87.4 Mg a.i./kg-diet;	50211561 (Acceptable)	Decreased eggs laid, and %14-day survivors of hatchlings
Mammals					
Acute Oral	TGAI (98.67)	Rat (*Rattus norvegicus*)	LD_{50}: > 5000 mg/kg	50211349 (Acceptable)	Practically non-toxic
Chronic (2-generation reproduction)	TGAI (98.67)	Rat (*Rattus norvegicus*)	NOAEL = 26 LOAEL = 127 mg a.i./kg-bw/day (both sexes) NOAEC/LOAEC: 300/1500 mg a.i./kg- diet	50211379 (Acceptable)	Decreased pup weights observed in both male and female F1 pups (5-7%) and F2 pups (6-10%) at 1500 and 15000 ppm.
Terrestrial Invertebrates					
Acute contact (adult)	TGAI (98.67)	Honey bee (*Apis mellifera* L.)	LD_{50} = 0.0088 µg a.i./bee	50211465 (Acceptable)	Highly toxic
Acute contact (adult)	TGAI (98.67)	Bumblebee (*Bombus terrestris*)	LD_{50} > 0.120 µg a.i./bee	50211466 (Acceptable)	37% mortality at highest dose, impairment and slow movement at 0.03 ug a.i./bee and greater; no other effects were observed in study
Acute contact (adult)	TEP (9.6)	Bumblebee (*Bombus terrestris*)	LD_{50} = 0.122 µg a.i./bee	50325608 (Acceptable)	Highly toxic
Acute oral (adult)	TGAI (98.67)	Honey bee (*Apis mellifera* L.)	LD_{50} = 0.0149 µg a.i./bee	50211465 (Acceptable)	Highly toxic
Acute oral (adult)	TGAI (98.67)	Bumblebee (*Bombus terrestris*)	LD_{50} = 0.0195 µg a.i./bee	50211466 (Acceptable)	Highly toxic

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value[1]	MRID or ECOTOX No./ Classification	Comments
Acute oral (adult)	TEP (9.6)	Bumblebee (*Bombus terrestris*)	LD_{50} = 0.0139 µg a.i./bee	50325608 (Acceptable)	Highly toxic
Chronic oral (adult)	TGAI (98.67)	Honey bee (*Apis mellifera* L.)	10-day NOAEL = 0.00062 µg a.i./bee/day (0.018 mg a.i./kg- diet) LOAEL = 0.0010 µg a.i./bee/day (0.034 mg a.i./kg-diet)	50211469 (Supplemental)	30% mortality at the LOAEC Supplemental because the study did not analytically measure concentrations
Acute oral (larval)	TGAI (98.67)	Honey bee (*Apis mellifera* L.)	8-day LC_{50} > 0.88 mg a.i./kg-diet LD_{50} > 0.029 µg a.i./larva/day	50211471 (Acceptable)	28% mortality at highest dose compared to controls
Chronic oral (larval)	TGAI (98.67)	Honey bee (*Apis mellifera L.*)	22-day NOAEC = 0.00229 mg a.i./kg-diet (0.00008 µg a.i./larva/day) LOAEC = 0.00696 mg a.i./kg-diet (0.00027 µg a.i./larva/day)	50211472 (Acceptable)	Pupal Mortality Test Termination Mortality and Adult Emergence NOAEL = 0.0008 ug a.i./larva/day LOAEL = 0.0022 ug a.i./larva/day Based on 18% increased mortality (reduced emergence) relative to the negative control
Terrestrial and Wetland Plants					
Seedling Emergence	TEP (9.6)	Monocots: *Zea mays* (corn), *Triticum aestivum* (wheat), *Allium cepa* (onion), *Lolium perenne* (ryegrass) Dicots: *Beta vulgaris* (sugar beet), *Lactuca sativa* (lettuce); *Brassica napus*	21-day Dicots (cabbage and sugar beet): EC_{25} = Not Reliable Sugar beet Survival NOAEC < 0.0023 lb a.i./acre Cabbage Survival NOAEC = 0.014 lb a.i./acre Monocots No Effects: EC_{25} > 0.091 lb a.i./acre; NOAEC = 0.091 lb a.i./acre)	50325617 (Acceptable; Supplemental for cabbage and sugar beet)	The most sensitive dicots were sugar beet and cabbage based on survival. The observations did not manifest in a dose response manner and are highly uncertain. No other dicots or monocots showed effects.

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value[1]	MRID or ECOTOX No./ Classification	Comments
Vegetative Vigor	TEP (9.6)	(oilseed rape), *Brassica oleracea* (cabbage), Glycine *max* (soybean), *Lycopersicon esculentum* (tomato)	21-day No observed effects to any species: EC_{25} > 0.091 lb a.i./acre NOAEC = 0.091 lb a.i./acre)	50325616 (Acceptable)	--

TGAI=Technical Grade Active Ingredient; TEP= Typical end-use product; a.i.=active ingredient

[1] NOAEC and LOAEC are reported in the same units.

>Greater than values designate non-definitive endpoints where no effects were observed at the highest level tested, or effects did not reach 50% at the highest concentration tested (USEPA, 2011).

< Less than values designate non-definitive endpoints where growth, reproductive, and/or mortality effects are observed at the lowest tested concentration.

6.3 Incident Data

A review on August 2, 2022 of the Incident Data System, which is maintained by the Agency's Office of Pesticide Programs, indicates that there have been no reported incidents associated with the use of broflanilide. No aggregate incidents have been reported by registrants for fish, wildlife, plants, or other non-target species as of June 10, 2022.

The number of actual incidents associated with broflanilide may be higher than what is reported to the Agency. Incidents may go unreported since side effects may not be immediately apparent or readily attributed to the use of a chemical. Although incident reporting is required under FIFRA Section 6(a)(2), the absence of reports in IDS does not indicate that the chemical has no effects on wildlife; rather, it is possible that incidents are unnoticed and unreported.

7 Analysis Plan

7.1 Overall Process

This assessment uses a weight of evidence approach that relies heavily, but not exclusively, on a risk quotient (RQ) method. RQs are calculated by dividing an estimate environmental concentration (EEC) by a toxicity endpoint (*i.*e., EEC/toxicity endpoint). This is a way to determine if an estimated concentration is expected to be above or below the concentration associated with the effects endpoint. The RQs are compared to regulatory levels of concern (LOCs). The LOCs for non-listed species are meant to be protective of community-level effects. For acute and chronic risks to vertebrates, the LOCs are 0.5 and 1.0, respectively, and for plants, the LOC is 1.0. The acute and chronic risk LOCs for bees are 0.4 and 1.0, respectively. In addition to RQs, other available data (*e.g.*, incident data) can be used to help understand the potential risks associated with the use of the pesticide.

8 Aquatic Organisms Risk Assessment

8.1 Aquatic Exposure Assessment

Aquatic exposure modeling was performed using the PWC model (version 2.001) to estimate surface water EECs. The information concerning the model can be found on the EPA Water Models web-page[1].

8.1.1 Model Inputs

Table 8-1 provides the PWC model input parameters, which were based on the maximum annual application rates and application intervals for the proposed uses. It also includes PWC scenarios, environmental fate properties and spray drift factors used in the PWC modeling. Environmental fate input parameter values for broflanilide are also presented. Input parameters were selected in accordance with EFED's "*Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides*," Version 2.1 (USEPA, 2009) and "*Guidance for Selecting Input Parameters for Modeling Pesticide Concentrations in Groundwater Using the Pesticide Root Zone Model*," Version 1 (USEPA 2013).

Table 8-1. PWC Input Parameters for Broflanilide

Parameter	Input Value and Unit	Comment	Source
Scenarios	<u>Poultry Litter Amendment:</u> IAcornstd ILCornSTD. INCornStd KSCornStd MNCornStd MScornSTD NCcornESTD NECornStd OHCornSTD PAcornSTD <u>Perimeter Treatment[A]:</u> CAresidentialRLF ResidentialBSS	All 10 standard scenarios for corn for poultry litter amendment to agricultural fields Non-standard residential scenarios for perimeter treatment.	PWC Scenarios
Maximum Single Application Rate lbs a.i./A *[Kg a.i./ha]*	<u>Poultry Litter Amendment:</u> 0.020 [0.022] for 2.0 tons/A 0.040 [0.045] for 4.0 tons/A 0.080 [0.090] for 8.0 tons/A 0.125 [0.140] for 12.5 tons/A <u>Perimeter Treatment:</u> 0.018 [0.02]	Single field application rates dependent on litter treatment rate (ton/A) Label directions	Appendix A Proposed label
Applications per Year	1 (poultry litter amendment) 8 (perimeter treatment)	Label directions	Table 2

[1] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment

Parameter	Input Value and Unit	Comment	Source
Initial Application Date	Poultry Litter Amendment: Pre-emergence: -10 [B]	Same as other poultry litter assessments	USEPA, 2017 USEPA, 2019
	Perimeter Treatment: 03-01 04-01 05-01 06-01 07-01 08-01 09-01 10-01	First of the month centered around the warmest months where beetles would be expected to have the highest pest pressure; adheres to the label requirement of no more than 8 applications per year no less than 4 weeks apart	Assumed
Application Interval (days)	none (poultry litter amendment) 4 weeks (perimeter treatment)	Single application for poultry litter Label directions for perimeter treatment	Assumed for poultry litter Proposed label for perimeter treatment
Application Method	Ground	Label directions	Proposed label
Spray drift and application efficiency	Spray Drift Fraction: 0 Application Efficiency: 1.0	Surface application of dry, solid manure is an effective application method for applying dry, bulky animal wastes such as poultry litter (USEPA 2017b)	Input Guidance [C]
Hydrolysis ($t_{1/2}$)	0 (stable)	stable	MRID 50211328
Aerobic soil metabolism ($t_{1/2}$) @25°C	2198 days	Represents the 90th %ile upper confidence limit on the mean of four (829, 1485, 2220, 2135d) half-lives	Input Guidance[D] MRID 50211427[E] MRID 50211430
Aerobic aquatic metabolism ($t_{1/2}$) @ 20°C	Total Water/Sediment System 1934 days	Represents the 90th %ile upper confidence limit on the mean of two (945, 1430d) half-lives	Input Guidance[D] MRID 50211437
Anaerobic aquatic metabolism ($t_{1/2}$) @20°C	Total Water/Sediment System 1972 days	Represents the 90th %ile upper confidence limit on the mean of two (871, 1411d) half-lives	Input Guidance[D] MRID 50211438
Aquatic photolysis ($t_{1/2}$) @25°C	80.0 days @ pH 7.0	---	MRID 50211329
Vapor pressure @ 25°C	6.6×10^{-11} Torr	---	MRID 50211316
Solubility in water	0.71 mg/L	---	
Henry's Law constant	3.32×10^{-9} (Unitless)	---	PWC model estimation
Molecular weight	663.29	Parent compound value	MRID 50211316
Partition coefficient K_F (mL/g)	177 mL/g (parent)	Parent broflanilide average K_F mL/g (246, 113, 16,181,248,and 158)	MRID 50211432

Parameter	Input Value and Unit	Comment	Source
[A] In the absence of standard scenario for perimeter treatments, the non-standard RLF and BSS scenarios were used as surrogate scenarios to represent perimeter treatments of broflanilide. [B] 10 days before crop emergence [C] USEPA, 2013. Guidance on modeling off-site deposition of pesticides via spray drift for ecological and drinking water assessments. [D] USEPA, 2009. http://www.epa.gov/oppefed1/models/water/input_parameter_guidance.htm [E] Since the reported DT_{50} was based on 20°C for this study, the half-life value was adjusted to 25°C based on a Q10 of 2.0 before calculating the upper-bound 90th percentile on the mean of all soils.			

8.1.2 Model Outputs

Estimated environmental concentrations (EEC) of broflanilide in surface water are summarized in **Table 8-2**. For poultry litter treated agricultural fields, EECs will be a function of the poultry litter treatment rate (tons/A). The maximum 1-in-10-year EECs of **5.58 µg/L** for the 1-day mean, **5.53 µg/L** for the 21-d mean, and **5.49 µg/L** for the 60-d mean concentration in surface water were estimated based on the maximum annual use rate for corn of 0.125 lbs. a.i./A using poultry litter treatment field application of 12.5 tons/A. The maximum 1-in-10-year 1-day and 21-day mean pore water and bulk sediment EECs are **6.55 µg/L** and **6.13 µg/L** in pore water and **29,032 µg/kg** and **27,169 µg/kg-OC** in organic carbon adjusted sediment. EECs from lower (2-8 tons/A) poultry litter and perimeter treatment rates are also listed below. Example outputs from the model runs are provided in **Appendix B**.

Table 8-2. Surface Water EECs for Broflanilide

Use	PWC Scenario	Poultry Litter Treatment (tons/A)	Field App Rate (lbs. a.i./A)	1-in-10-year mean EEC						
				Water Column (µg/L)			Pore-Water (µg/L)		Bulk Sediment (µg/kg-organic carbon)[1]	
				1-day	21-day	60-day	1-day	21-day	1-day	21-day
Poultry Litter (Corn)	IAcornstd	2.0	0.02	0.58	0.58	0.58	0.63	0.60	2813	2663
	ILCornSTD			0.78	0.78	0.78	0.86	0.83	3830	3673
	INCornStd			0.45	0.45	0.44	0.44	0.44	1941	1939
	KSCornStd			0.66	0.64	0.64	0.65	0.65	2889	2865
	MNCornStd			0.48	0.46	0.46	0.46	0.46	2036	2037
	MScornSTD			**0.88**	**0.87**	**0.86**	**1.03**	**0.96**	**4564**	**4270**
	NCcornESTD			0.50	0.50	0.50	0.53	0.51	2347	2269
	NECornStd			0.69	0.69	0.68	0.69	0.69	3071	3057
	OHCornSTD			0.71	0.71	0.70	0.77	0.74	3411	3262
	PAcornSTD			0.54	0.54	0.53	0.56	0.54	2474	2411
	IAcornstd	4.0	0.04	1.19	1.18	1.18	1.30	1.23	5752	5446
	ILCornSTD			1.60	1.60	1.59	1.77	1.69	7837	7513
	INCornStd			0.93	0.91	0.90	0.90	0.89	3970	3966
	KSCornStd			1.35	1.32	1.31	1.33	1.32	5907	5863
	MNCornStd			0.97	0.94	0.94	0.94	0.94	4164	4165
	MScornSTD			**1.80**	**1.78**	**1.77**	**2.10**	**1.97**	**9331**	**8733**
	NCcornESTD			1.02	1.02	1.02	1.08	1.05	4799	4639

Use	PWC Scenario	Poultry Litter Treatment (tons/A)	Field App Rate (lbs. a.i./A)	1-in-10-year mean EEC						
				Water Column (µg/L)			Pore-Water (µg/L)		Bulk Sediment (µg/kg-organic carbon)[1]	
				1-day	21-day	60-day	1-day	21-day	1-day	21-day
	NECornStd			1.41	1.40	1.40	1.42	1.41	6280	6253
	OHCornSTD			1.45	1.45	1.44	1.57	1.50	6976	6670
	PAcornSTD			1.10	1.10	1.08	1.14	1.11	5060	4932
	IAcornstd	8.0	0.08	2.37	2.37	2.36	2.60	2.46	11509	10897
	ILCornSTD			3.20	3.19	3.17	3.53	3.39	15669	15026
	INCornStd			1.86	1.83	1.81	1.79	1.79	7939	7934
	KSCornStd			2.70	2.64	2.62	2.66	2.64	11815	11722
	MNCornStd			1.94	1.89	1.88	1.88	1.88	8329	8329
	MScornSTD			**3.59**	**3.55**	**3.53**	**4.21**	**3.94**	**18662**	**17465**
	NCcornESTD			2.05	2.04	2.03	2.17	2.09	9602	9278
	NECornStd			2.82	2.81	2.79	2.83	2.82	12560	12507
	OHCornSTD			2.90	2.89	2.88	3.15	3.01	13957	13345
	PAcornSTD			2.19	2.19	2.16	2.28	2.22	10121	9863
	ILCornSTD	12.5	0.125	3.69	3.68	3.67	4.04	3.82	17904	16946
	INCornStd			4.98	4.96	4.94	5.50	5.27	24375	23372
	KSCornStd			2.89	2.84	2.81	2.79	2.78	12351	12338
	MNCornStd			4.19	4.10	4.07	4.14	4.11	18379	18237
	MScornSTD			3.02	2.94	2.93	2.92	2.92	12955	12959
	NCcornESTD			**5.58**	**5.53**	**5.49**	**6.55**	**6.13**	**29032**	**27169**
	NECornStd			3.18	3.18	3.16	3.37	3.26	14933	14436
	OHCornSTD			4.38	4.37	4.34	4.41	4.39	19541	19452
	PAcornSTD			4.52	4.50	4.48	4.90	4.68	21709	20760
Perimeter Treatment	CAresidentialRLF	--	0.02 x 8	**3.41**	**3.41**	**3.36**	**3.55**	**3.46**	**15744**	**15341**
	ResidentialBSS			1.06	1.03	1.01	1.00	1.00	4421	4420

Maximum EECs are shown in **bold**. – not applicable

[1]The benthic conversion factor is 177.4 and the fraction organic carbon (foc) is 0.04 for the EPA pond.

8.1.3 Monitoring

Since broflanilide is a recently registered pesticide in 2021, there are no water monitoring data to report. The Water Quality Portal[2] was searched on September 23, 2022 and broflanilide was not included as a search analyte.

8.2 Aquatic Organism Risk Characterization

RQs are calculated by dividing acute and chronic EECs by their respective most sensitive toxicity endpoint (*i.e.*, EEC/toxicity endpoint). For evaluating acute risk to aquatic animals, the 1-day average EEC is used as the acute EEC; for aquatic vertebrates, the 60-day average EEC is used

[2] https://www.waterqualitydata.us/

for the chronic EEC while the 21-day average EEC is used as the chronic EEC for aquatic invertebrates.

8.2.1 Aquatic Vertebrates

Table 8-3 summarizes the acute and chronic RQ values for freshwater and estuarine/marine fish based on the highest EECs from each modeled use assumption (**Table 8-2**). Based on the available data, freshwater fish acute and chronic fish RQs (acute: <0.01-0.02; chronic: 0.02-0.11) did not exceed the acute risk to non-listed species LOC (0.5) nor the chronic risk LOC (1.0), suggesting a low risk to freshwater fish.

The ecological effects database is incomplete for chronic exposures to freshwater fish. The available chronic freshwater fish study did not use the most sensitive species (*e.g.*, bluegill or rainbow trout) based on acute toxicity, therefore there is uncertainty regarding the protectiveness of the available endpoint. Several acute freshwater fish studies are available. The most sensitive of these was a test on the bluegill (*Lepomis macrochirus*) which resulted in an LC_{50} of 251 µg a.i./L. A similar response was observed with rainbow trout. The steep dose responses contribute to uncertainty in the estimated acute endpoints for these studies. These data suggest that broflanilide is classified as highly toxic to freshwater fish on an acute exposure basis. An early life-stage chronic fish toxicity studies testing the sensitivity of fathead minnow (*Pimphales promelas*) is available. In the fathead minnow study, there were statistically significant 9% and 85% reductions in larval survival at 147 and 475 µg a.i./L respectively; therefore, the NOAEC was established at 51 µg a.i./L. Given the apparent contrast in toxicity reflected in the available acute data for freshwater fish, it is unknown if bluegill or rainbow trout would result in more sensitive endpoints that those provided in the fathead minnow test. Since the potential for risk is low for freshwater fish, these uncertainties are not of concern.

Also, for acute estuarine/marine fish, the EECs are orders of magnitude below the highest tested concentration tested in the study which did not result in 50% or greater mortality. Moreover, the chronic RQs for estuarine/marine fish (range: 0.08-0.15) did not exceed the chronic LOC (1). Therefore, the potential for acute or chronic risk to estuarine/marine fish and aquatic-phase amphibians, for which fish serve as surrogates, from exposure as a result of the proposed uses of broflanilide is expected to be low.

Table 8-3. Acute and Chronic Vertebrate Risk Quotients for Non-listed Species

Use Sites (Field Application Rate, lb a.i./A)	1-in-10-Yr EEC (µg/L)		Risk Quotient			
			Freshwater		Estuarine/Marine	
	Daily Mean	60-day Mean	Acute[1]	Chronic[2]	Acute[1]	Chronic[2]
			LC_{50} = 251 µg a.i./L	NOAEC = 51 µg a.i./L	LC_{50} >1300 µg a.i./L	NOAEC = 11 µg a.i./L
Poultry Litter (0.02)	0.87	0.85	<0.01	0.02	NC	0.08

Use Sites (Field Application Rate, lb a.i./A)	1-in-10-Yr EEC (µg/L)		Risk Quotient			
			Freshwater		Estuarine/Marine	
	Daily Mean	60-day Mean	Acute[1]	Chronic[2]	Acute[1]	Chronic[2]
			LC_{50} = 251 µg a.i./L	NOAEC = 51 µg a.i./L	LC_{50} >1300 µg a.i./L	NOAEC = 11 µg a.i./L
Poultry Litter (0.04)	1.78	1.75	0.01	0.03	NC	0.16
Poultry Litter (0.08)	3.55	3.49	0.01	0.07	NC	0.32
Poultry Litter (0.125)	5.53	5.44	0.02	0.11	NC	0.50
Perimeter treatment (0.02 x 8)	3.70	3.30	0.01	0.06	NC	0.27

Bolded values exceed the LOC for acute risk to non-listed species of 0.5 or the chronic risk LOC of 1.0. The endpoints listed in the table are the endpoint used to calculate the RQ.
NC: Not calculable
[1] The EECs used to calculate these RQs are based on the 1-in-10-year peak 1-day average value from **Table 8-3.**
[2] The EECs used to calculate these RQs are based on the 1-in-10-year 60-day average value from **Table 8-3**.

8.2.2 Aquatic Invertebrates

Invertebrates in the Water Column

Table 8-4 summarizes acute and chronic RQ values for freshwater and estuarine/marine water column invertebrates based on comparisons to EECs in overlying water.

The acute endpoint for *Daphnia* was non-definitive, so RQs were not calculated; however acute risk is presumed to be low for these taxa because the highest tested concentrations are orders of magnitude greater than the EECs and did not result in 50% or greater mortality in the studies. Freshwater invertebrate chronic RQs (range: 0.15-0.92) based on the available chronic *Daphnia* study did not result in chronic LOC (1) exceedances.

The estuarine/marine invertebrate acute RQs (range 40 to 257) and chronic EECs are 478 to 3039 times higher than the chronic mysid endpoint. A NOAEC was not established in available mysid chronic study so RQs were not calculated. Based on the LOAEC of 0.0018 µg a.i./L, where there was a 17% reduced survival for offspring and 22% reduced reproduction, the EECs are expected to result in chronic risk to estuarine/marine aquatic invertebrates.

The results for estuarine/marine invertebrates may reflect a potential risk concern for non-crustacean aquatic invertebrates in freshwater ecosystems as well. The differential sensitivity of *Daphnids* versus mysids, may be a reflection of their different taxonomies rather than the freshwater versus salt water. Additional consideration of freshwater invertebrate risks is provided in the benthic invertebrate discussion below.

Table 8-4. Acute and Chronic Aquatic Invertebrate (Exposed in the Water-Column) Risk Quotients

Use Sites (Field Application Rate, lb a.i./A)	1-in-10-Yr EEC (µg/L)		Risk Quotient			
			Freshwater		Estuarine/Marine	
	Daily Mean	21-day Mean	Acute[1]	Chronic[2]	Acute[1]	Chronic[2,3]
			LC_{50} >322 µg a.i./L	NOAEC = 5.93 µg a.i./L	LC_{50} = 0.0215 µg a.i./L	NOAEC < 0.0018 µg a.i./L
Poultry Litter (0.02)	0.87	0.86	NC	0.15	**40**	**>478**
Poultry Litter (0.04)	1.78	1.76	NC	0.30	**83**	**>978**
Poultry Litter (0.08)	3.55	3.52	NC	0.59	**165**	**>1955**
Poultry Litter (0.125)	5.53	5.47	NC	0.92	**257**	**>3039**
Perimeter treatment (0.02 x 8)	3.70	3.46	NC	0.58	**172**	**>1922**

Bolded values exceed the LOC for acute risk to non-listed species of 0.5 or the chronic risk LOC of 1.0. The endpoints listed in the table are the endpoint used to calculate the RQ.
[1] The EECs used to calculate this RQ are based on the 1-in-10-year peak 1-day average value from **Table 8-2**.
[2] The EECs used to calculate this RQ are based on the 1-in-10-year 21-day average value from **Table 8-2**.
[3] Ratios of the EEC to the endpoint were provided to illustrate the magnitude of the EECs exceeding the concentration in the study where effects were observed.

Invertebrates in the sediment

Several acute and chronic benthic invertebrate toxicity studies are used to evaluate the potential risks of broflanilide to sediment dwelling invertebrates. These include freshwater (*Chironomus* and *Hyalella*) and estuarine marine (*Leptocheirus*) taxa. These data were evaluated against measures of exposure in terms of the mass of broflanilide in bulk sediment, organic carbon, and pore water as estimated by the PWC modeling for corn uses. When endpoints in the available studies could not be calculated based on measured concentrations in pore water, estimated pore water concentrations were derived using the measured bulk sediment (µg a.i./kg-sediment) in the study and the mean K_F for broflanilide (177 L/kg-sediment). The K_F was selected over the K_{FOC} because the fate characteristics indicate that broflanilide sorption to sediment is best characterized by the K_F, which accounts for sorption to the silts, clays, and organic matter.

Risk quotients for freshwater and estuarine/marine invertebrates exceed the acute LOC (0.5) for all proposed uses from sediment and pore water based EECs (**Table 8-5**). Similar to the water column risks discussed above, the PWC modeling and subsequently the RQs consider 30 years of annual use. Acute RQs exceeded the LOC for both freshwater invertebrates (*Chironomus* and *Hyalella*) and estuarine/marine (*Leptocheirus*) invertebrates for poultry litter and perimeter spray from both pore-water and sediment exposure, indicating acute risk to benthic sediment invertebrates.

Risk quotients exceed the chronic LOCs (1.0) for all proposed uses for both freshwater and estuarine/marine invertebrates from both sediment and pore-water exposure (**Table 8-5**). Moreover, comparisons between EECs and sediment invertebrate LOAEC endpoints, suggest adverse reproductive and survival effects from the proposed uses to sediment-dwelling invertebrates. EECs in benthic sediments from poultry litter use (range: 4,227-26,898 µg a.i./kg-sediment) and perimeter spray applications (13,762 µg a.i./kg-sediment) were orders of magnitude greater than freshwater sediment invertebrate LOAECs for *Chironomus* (4.7 µg/kg dry; 36% reduction in percent emergence and 20% reduction in survival) and *Hyalella* (1.7 µg/kg-sediment; 46% reduction in male-to-female ratio), as well as orders of magnitude greater than the estuarine/marine sediment invertebrate LOAEC for *Leptocheirus* (8.4 µg/kg-sediment; 36% reduction in percent emergence and 12% reduction in survival). These results suggest chronic risks to sediment dwelling invertebrates from the proposed uses.

Although low acute and chronic risks to freshwater column invertebrates were identified using freshwater *Daphnia,* acute and chronic risk to freshwater sediment invertebrates, *Chironomus and Hyalella* were identified from pore water exposure. Analyses with *Chironomus* and *Hyalella* suggest that *Daphnia* may not be reflective of the potential risk to other water column invertebrates in freshwater systems, and adverse effects to freshwater invertebrates may still be possible.

Conclusions for water column and sediment dwelling invertebrates

Exposure estimates for all modeled scenarios, including the lower end estimates for rates of poultry litter amendments, result in acute and chronic risk concerns for freshwater and estuarine/marine invertebrates. These results reflect that broflanilide has the potential to result in acute and chronic risk to water column and sediment dwelling invertebrates, and that repeated use can considerably increase these risks over time due to the persistence of broflanilide. Additionally, because of the propensity of broflanilide to bind with and accumulate in sediments, the risks to benthic invertebrates and invertebrates interacting with the sediments are expected to be greater than the water column invertebrates that don't interact with sediment.

Table 8-5. Maximum Acute and Chronic Freshwater and Estuarine/Marine Benthic Invertebrate Risk Quotients (RQs).

Exposure Basis		Test Species	*Acute LC50 based RQs[1]*			*Chronic NOAEC based RQs[2]*		
			Chironomus Freshwater	*Hyalella Freshwater*	*Leptocheirus Estuarine/ Marine*	*Chironomus Freshwater*	*Hyalella Freshwater[3]*	*Leptocheirus Estuarine/ Marine*
Benthic Invertebrate comparisons to Pore Water Based EECs		**Endpoints (µg a.i./L)**	0.211	0.461	0.0793	0.024	< 0.039	0.0213
Scenario (Field Application Rate, lb a.i./A)	**Maximum 1-day mean EECs (ug a.i./L-pore water)**	**Maximum 21-day mean EECs (ug a.i./L-pore water)**						
Poultry Litter (0.02)	1.0	0.95	**4.7**	**2.2**	**13**	**40**	**>24**	**45**
Poultry Litter (0.04)	2.1	2.0	**10**	**4.6**	**26**	**83**	**>51**	**94**
Poultry Litter (0.08)	4.2	3.9	**20**	**9.1**	**53**	**163**	**>100**	**183**
Poultry Litter (0.125)	6.5	6.1	**31**	**14**	**82**	**254**	**>156**	**286**
Perimeter treatment (0.02 x 8)	3.1	3.1	**15**	**6.7**	**39**	**129**	**>79**	**146**
Benthic Invertebrate comparisons to Bulk Sediment Based EECs		**Test Species**	*Acute LC50 based RQ[1]*			*Chronic NOAEC based RQs[2]*		
			Chironomus Freshwater	*Hyalella Freshwater*	*Leptocheirus Estuarine/ Marine*	*Chironomus Freshwater*	*Hyalella Freshwater*	*Leptocheirus Estuarine/ Marine*
		Endpoints (µg a.i./kg-sediment)	9.99	13.5	14	1.5	< 1.7	3.8
Scenario	**Maximum 1-day mean EECs (ug a.i./kg-sediment)**	**Maximum 21-day mean EECs (ug a.i./kg-sediment)**						
Poultry Litter (0.02)	4515	4227	**452**	**334**	**323**	**2818**	**>2486**	**1112**
Poultry Litter (0.04)	9238	8644	**925**	**684**	**660**	**5763**	**>5085**	**2275**
Poultry Litter (0.08)	18476	17292	**1849**	**1369**	**1320**	**11528**	**>10172**	**4551**
Poultry Litter (0.125)	28743	26898	**2877**	**2129**	**2053**	**17932**	**>15822**	**7078**
Perimeter treatment (0.02 x 8)	13780	13762	**1379**	**1021**	**984**	**9175**	**>8095**	**3622**

The endpoints listed in the table are the endpoint used to calculate the RQ.

[1] The EECs used to calculate this RQ are based on the 1-in-10-year peak 1-day average value from **Table 8-2**.

[2] The EECs used to calculate this RQ are based on the 1-in-10-year 21-day average value from **Table 8-2**

[3] Ratios of the EEC to the endpoint were provided to illustrate the magnitude of the EECs exceeding the concentration in the study where effects were observed.

8.2.3 Aquatic Plants:

Potential risks to aquatic non-vascular plants are estimated using the 1-in-10-year daily average concentration based on exposure from runoff and drift. For evaluating risks to non-listed plants, the EEC is compared to the most sensitive IC_{50} value and the resulting RQ is then compared to the LOC of 1.0. **Table 8-6** summarizes RQ values for non-vascular aquatic plants. Risk quotient values for non-vascular plants were below the LOCs and indicate that potential risk to non-listed species is low. Moreover, for vascular plants, the EECs are orders of magnitude below the highest tested concentration in the study which did not result in 50% or greater mortality. Therefore, the potential for risk to aquatic vascular and non-vascular plants from exposure as a result of the proposed uses of broflanilide is expected to be low.

Table 8-6. Aquatic Plant Risk Quotients for Non-listed Species

Use Sites (Field Application Rate)	1-in-10 Year Daily Mean EEC (µg/L)	Risk Quotients	
		Vascular	Non-vascular
		IC_{50} >630 µg a.i./L	IC_{50} = 570 µg a.i./L
Poultry Litter (0.02)	0.87	NC	<0.01
Poultry Litter (0.04)	1.78	NC	<0.01
Poultry Litter (0.08)	3.55	NC	0.01
Poultry Litter (0.125)	5.53	NC	0.01
Perimeter treatment (0.02 x 8)	3.70	NC	0.01

The LOC for non-listed plants is 1. The endpoints listed in the table are the endpoint used to calculate the RQ.

9 Terrestrial Vertebrates Risk Assessment

9.1 Terrestrial Vertebrate Exposure Assessment

9.1.1 Dietary Items on the Treated Field

Terrestrial wildlife exposure estimates are typically calculated for birds and mammals by emphasizing the dietary exposure. Broflanilide is applied through spray methods, which includes handheld sprayers. Broflanilide residues may also be present in manure following broflanilide applications in poultry houses. Therefore, potential dietary exposure for terrestrial wildlife in this assessment is based on consumption of broflanilide residues on food items following spray application to perimeters of poultry houses and following spray of manure on fields where the applied manure from poultry house operations may contain broflanilide residues resulting in potential contamination of potential food items in the field and/or contaminated food items in the poultry litter.

Rates used in modeling for broflanilide applications are presented below for the perimeter spray uses and the poultry manure use. EECs are based on application rates, number of applications, and intervals presented in **Table 9-1**.

Table 9-1. Application Rates Used for T-REX Modeling for Foliar and Soil Applications of Broflanilide.

Use	Application Type	Application rate (lbs a.i./A)	Number of applications	Application intervals	Maximum annual application rate (lbs a.i./A)
Poultry Manure	Soil[1]	0.02 (BEAD)[2,3] 0.04 (MRID)[3] 0.08 (Avg. N)[3] 0.125 (Max. N)[3]	1	0	0.125
Poultry house perimeter spray	Foliar (ground)	0.018	8	30 days	0.14 lbs./A/yr

[1]Assumes the applied manure contains broflanilide residues in poultry litter using the most conservative assumptions regarding broflanilide application use with no degradation and maximum manure applied based on crop nitrogen requirements.

[2]Poultry manure application rate information collected by the Biological and Economic Analysis Division (BEAD; USEPA 2017d) suggests that growers would rarely use more than 2-3 tons of litter per acre.

[3]Since the broflanilide application rate can vary by the nitrogen requirement of the crop (mass applied as litter application), multiple scenarios were modeled to hypothetically characterize poultry litter application to agricultural fields.

Poultry House Perimeter Spray and Poultry House Manure Soil Exposure Estimates

T-REX v.1.5.2 was used to calculate EECs for birds and mammals via dietary residues resulting from poultry house perimeter spray applications and poultry manure field applications. The application rate for perimeter spray was modeled as the highest single application rate (0.018 lbs a.i./A, x1) and as 8 applications (0.018 lbs a.i./A, x 8, 30-d interval). The poultry manure application was modeled as the highest single application rate of 0.125 lbs a.i./A. EFED's default foliar dissipation rate of 35 days was used for this analysis to estimate dissipation after each application. Consideration of additional half-life values for characterization was not done based on the final EECs and subsequent LOC exceedances (or lack thereof) further explained in the risk description sections. The default foliar dissipation half-life only factors into calculated EECs for ground spray applications. Upper-bound Kenaga nomogram values are used to derive EECs for broflanilide exposures to terrestrial mammals and birds **(Tables 9-2)**.

Table 9-2. Summary of Dietary (mg a.i./kg-diet) and Dose-based EECs (mg a.i./kg-bw) as Food Residues for Birds, Reptiles, Terrestrial-Phase Amphibians and Mammals from Labeled Uses of Broflanilide(T-REX v. 1.5.2, Upper Bound Kenaga)

Food Type	Dietary-Based EEC (mg/kg-diet)	Dose-Based EEC (mg/kg-body weight)					
		Birds			Mammals		
		Small (20 g)	Medium (100 g)	Large (1000 g)	Small (15 g)	Medium (35 g)	Large (1000 g)
Poultry litter soil amendment (0.125 lbs a.i./A, 1x)							
Short grass	30	34	19	8.7	29	20	4.6
Tall grass	14	16	8.9	4.0	13	9.1	2.1
Broadleaf plants/small insects	17	19	11	4.9	16	11	2.6
Fruits/pods/seeds (dietary only)	2	2.1	1.2	0.55	1.8	1.2	0.29
Arthropods	12	13	7.6	3.4	11	7.7	1.8
Seeds (granivore)[1]	--	0.47	0.27	0.12	0.40	0.27	0.06
Poultry house perimeter spray (0.018 lbs a.i./A, 1x)							
Short grass	4.3	4.9	2.8	1.3	4.1	2.9	0.66
Tall grass	2.0	2.3	1.3	0.58	1.9	1.3	0.30
Broadleaf plants/small insects	2.4	2.8	1.6	0.71	2.3	1.6	0.37
Fruits/pods/seeds (dietary only)	0.27	0.31	0.18	0.08	0.26	0.18	0.04
Arthropods	1.7	1.9	1.1	0.49	1.6	1.1	0.26
Seeds (granivore)[1]	--	0.04	0.02	0.07	0.04	0.02	0.07
Poultry house perimeter spray (0.018 lbs a.i./A, 8x, 30-d interval)							
Short grass	9.6	11	6.2	2.8	9.1	6.3	1.5
Tall grass	4.4	5.0	2.8	1.3	4.2	2.9	0.67
Broadleaf plants/small insects	5.4	6.1	3.5	1.6	5.1	3.5	0.82
Fruits/pods/seeds (dietary only)	0.6	0.68	0.39	0.17	0.57	0.39	0.09
Arthropods	3.7	4.3	2.4	1.1	3.6	2.5	0.57
Seeds (granivore)[1]	--	0.15	0.09	0.04	0.13	0.09	0.02

[1] Seeds presented separately for dose – based EECs due to difference in food intake of granivores compared with herbivores and insectivores. This difference reflects the difference in the assumed mass fraction of water in their diets.

9.2 Terrestrial Vertebrate Risk Characterization

Poultry House Perimeter Spray and Manure Applications to the Crop Field

RQ values for birds and mammals, are generated based on the upper-bound EECs discussed above. The RQs for acute-based exposure to birds and mammals were not quantifiable as available data are non-definitive and indicate that broflanilide is practically non-toxic (see **Section 6**). Comparisons of maximum EECs to body weight and diet-adjusted endpoints show that EECs are orders magnitude below the highest tested concentrations in the studies which showed no effects to birds and mammals. Therefore, based on the available data, the potential acute dose or dietary risk to birds and mammals foraging on the application site is considered low for poultry house perimeter spray and poultry manure field applications.

For perimeter spray uses, chronic dietary RQs based on upper-bound Kenaga values at the proposed maximum single application rate of 0.018 lbs a.i./A, (at 8 applications and 30-d intervals) ranged from 0.02 – 0.32 for birds and <0.01 – 0.03 for mammals (dose based RQs for mammals ranged <0.01 – 0.16); therefore, RQs are below the chronic risk LOC at this proposed rate. Based on the available data, the potential for direct adverse effects on birds and mammals on a chronic exposure basis through diet from the proposed poultry house perimeter spray use is expected to be low.

For poultry manure applications to agricultural fields modeled at the highest single application rate of 0.125 lbs a.i./A, dietary-based chronic RQs ranged from 0.06-1.01. The RQ of 1.01 was greater than the avian chronic LOC (1) for only birds feeding on short grass. Although the RQ is greater than the LOCfor only birds feeding on short grass, this assessment concludes that chronic risk to birds is low considering that the modeled rate of 0.125 lbs a.i./A likely overestimates the rate that is used on the agricultural crops, and T-REX modeling likely overestimates potential contamination of diet food items on the field. Chronic RQs for mammals (dose-based RQ range: 0.01-0.50; dietary-based RQ range: 0.01-0.10) did not exceed the mammalian chronic LOC (1). Therefore, potential risk to mammals from poultry manure applications are considered low.

Residues in Aquatic Food Items For Terrestrial Vertebrates

Since the Kow of broflanilide is 5.2, broflanilide has the potential to bioaccumulate in fish and aquatic invertebrates. The KABAM model (KOW (based) Aquatic BioAccumulation Model) version 1.04 was used to evaluate the potential exposure and risk of direct effects to birds and mammals via bioaccumulation and biomagnification in aquatic food webs. KABAM is used to estimate potential bioaccumulation of hydrophobic organic pesticides in freshwater aquatic ecosystems and risks to mammals and birds consuming aquatic organisms which have bioaccumulated these pesticides. The bioaccumulation portion of KABAM is based upon work by Arnot and Gobas (2004) who parameterized a bioaccumulation model based on PCBs and some pesticides (*e.g.*, lindane, DDT) in freshwater aquatic ecosystems (Arnot and Gobas, 2004). KABAM relies on a chemical's octanol-water partition coefficient (KOW) to estimate uptake and elimination constants through respiration and diet of organisms in different trophic levels. Pesticide tissue residues are calculated for organisms at different levels of an aquatic food web. The model then uses pesticide tissue concentrations in aquatic animals to estimate dose- and dietary-based exposures and associated risks to mammals and birds (surrogate for amphibians and reptiles) consuming aquatic organisms. Seven different trophic levels including phytoplankton, zooplankton, benthic invertebrates, filter feeders, small-sized (juvenile) forage fish, medium-sized forage fish, and larger piscivorous fish, are used to represent an aquatic food web. Input scenarios and parameters were chosen to maximum exposures from and are presented in **Table 9-3**. For full KABAM model outputs see **Appendix C.**

Table 9-3. Bioaccumulation Model Input Values for Broflanilide.

Characteristic	Value	Comments/Guidance
Pesticide Name	Broflanilide	
Log Kow	5.2	MRID 50211316
Koc (L/kg OC)	7606	Mean Koc MRID 50211432
Time to steady state (TS; days)	45	No input necessary. This value is calculated automatically from the Log Kow value entered above.
Pore water EECs (µg/L)	Poultry litter application 1.03, 2.10, 4.21, 6.55 Perimeter spray 3.55	See **Table 8-2**
Water Column EECs (µg/L)	Poultry litter application 0.88, 1.80, 3.59, 5.58 Perimeter spray 3.41	See **Table 8-2**
Broflanilide Most sensitive Effects Endpoints		
Avian	LD_{50} (mg/kg-bw)	>2000[1]
	LC_{50} (mg/kg-diet)	>5000[1]
	NOAEC (mg/kg-diet)	29.7
Mammalian	LD_{50} (mg/kg-bw)	>5000[1]
	LC_{50} (mg/kg-diet)	NA
	NOAEC (mg/kg-bw)	300

[1]Non-definitive endpoint

Bioaccumulation in Birds and Mammals

The bioaccumulation modeling evaluated poultry litter application and poultry house perimeter spray application and was conducted to represent the maximum pore and overlying water EECs. **Table 9-4** summarizes avian and mammalian RQs derived from KABAM modeling; for full KABAM model outputs see **Appendix C.** For poultry litter applications, model input EECs were first selected from PWC scenarios which produced the maximum EECs for water column and pore water applications of broflanilide at application rates of 0.2, 0.4, 0.8, and 0.125 lbs a.i./A (see **Table 8-2**). For poultry house perimeter spray applications, model input EECs were selected from PWC scenarios which produced the maximum EECs for water column and pore water applications of broflanilide at an application rate of 0.02 lbs a.i./A x 8 applications.

For birds, there were dietary-based LOC exceedances from the proposed uses. Chronic dietary-based RQs were greater than the LOC at application rates of 0.04 lbs a.i./A (white pelican; RQ: 1.2), 0.08 lbs a.i./A (rails, herons, small osprey, and white pelican; RQs: 1.0-2.5), and 0.125 lbs a.i./A (all wildlife species; RQs: 1.3-3.9), but not 0.02 lbs a.i./A for poultry litter soil applications (Table 9-4). There were also chronic LOC exceedances for birds from poultry house perimeter spray applications (herons, small osprey, white pelican; RQ: 1.1-2.3) (**Table 9-4**). Dose- and dietary-based acute RQs could not be calculated due to non-definitive endpoints (>2000mg/kg-bw, and >5000 mg/kg-diet); however, acute RQs were below the acute LOC when modeling at the highest tested dose and diet-based concentrations (2000 mg/kg-bw and 5000 mg/kg-diet, respectively) for all uses and application rates. Taken together, there are chronic risk concerns for birds from poultry house perimeter spray applications and poultry litter soil applications at rates of 0.04 lbs a.i./A and greater.

For mammals, there were dose-based LOC exceedances from the proposed uses, but no dietary-based LOC exceedances. For poultry litter applications and at the maximum EECs, dose-based RQs were greater than the LOC for mammals at application rates of 0.04 lbs a.i./A (large river otter; RQ: 1.1), 0.08 lbs a.i./A (large mink, and small and large river otter; RQs: 1.0-2.0), and 0.125 lbs a.i./A (small and large mink, and small and large river otter; RQs: 1.3-3.9). RQs were below the LOC for applications at 0.02 lbs a.i./A for poultry litter soil applications (**Table 9-4**). For poultry spray perimeter applications, there were dose-based chronic LOC exceedances for birds from poultry house perimeter spray applications (herons, small osprey, white pelican; RQs: 1.1-2.3) (**Table 9-4**). Dietary-based chronic RQs were all below the LOC for all uses and application rates. Acute dose-based RQs could not be calculated for mammals due to non-definitive endpoints (>5000 mg/kg-bw); however, acute RQs were below the acute LOC when modeling at the highest tested concentration (5000 mg/kg-bw) for all uses and application rates indicating low acute risks to mammals eating aquatic organisms contaminated with broflanilide.

Taken together, there are chronic risk concerns for mammals and birds consumption of aquatic organisms contaminated with broflanilide residues from poultry house perimeter spray use and from poultry litter soil uses at applications rates of 0.04 lbs a.i./A and greater. There are no acute risk concerns for both birds and mammals for any uses from consumption of aquatic organisms contaminated with broflanilide.

Table 9-4. KABAM Modeling Results for Birds and Mammals

Organisms	PWC Scenario/ Concentration	Chronic RQ[1]	
		Dose-based	Dietary-based
Poultry litter soil amendment (0.125 lbs a.i./A, 1x)			
Birds	Max Water Column Concentration (5.58 µg/L)	NC	**1.3-3.9**
Mammals	Max Pore Water Concentration (6.55 µg/L)	**3.1-1.5**	≤0.39
Poultry litter soil amendment (0.08 lbs a.i./A, 1x)			
Birds	Max Water Column Concentration (3.59 µg/L)	NC	0.85-**2.5**
Mammals	Max Pore Water Concentration (4.21 µg/L)	0.43-**2.0**	≤0.25
Poultry litter soil amendment (0.04 lbs a.i./A, 1x)			
Birds	Max Water Column Concentration (1.80 µg/L)	NC	0.43-**1.3**
Mammals	Max Pore Water Concentration (2.10 µg/L)	0.22-**1.0**	≤0.13
Poultry litter soil amendment (0.02 lbs a.i./A, 1x)			
Birds	Max Water Column Concentration (0.88 µg/L)	NC	≤0.62
Mammals	Max Pore Water Concentration (1.03 µg/L)	0.11-0.49	≤0.06
Poultry house perimeter spray (0.02 lbs a.i./A, 8x)			
Birds	Max Water Column Concentration (3.41 µg/L)	NC	0.8-**2.3**
Mammals	Max Pore Water Concentration (3.55 µg/L)	0.41-**1.8**	≤0.236

[1]Acute LOC = 0.5; Chronic LOC=1.0; Bold=LOC exceedance[1]; NC = Not calculable

10 Terrestrial Invertebrate Risk Assessment

Broflanilide is a diamide insecticide that has larvicidal activity against many chewing pests. Nakao and Banba (2016) suggested that broflanilide is metabolized to desmethyl-broflanilide within the insect, which acts as a noncompetitive resistant-to-dieldrin (RDL) γ-aminobutyric acid (GABA) receptor antagonist. Because of its mode of action, risks to bees is anticipated. The following section discusses the potential exposure routes and extent of potential risks to adult and larval bees.

10.1 Bee Exposure Assessment

Broflanilide's fate characteristics (log Kow; Koc) and the propensity to sorb to sediments suggest that it is not likely systemic in plants and therefore exposure to bees through pollen and nectar contamination is likely to primarily occur through spray drift deposition on flowering attractive vegetation. This conclusion is supported by submitted plant residue studies on corn, rape and canola (MRIDs 50211477, 50211478, 50211643) which showed no detections of broflanilide in plant tissues, pollen and nectar. In the rape study, one replicate of three had a single unexplained detection of broflanilide at 0.0015 mg/kg, but did not fit a pattern suggesting systemic transport. The proposed use of broflanilide as a poultry manure for field crops means that systemic transport would be required to achieve exposures to honeybees, and is unlikely given the lack of support for systemic transport of broflanilide. Therefore, there's not likely a risk concern from this application method because of limited opportunity for contamination of flowering parts given that the surface application of dry, solid manure is an effective application method for applying dry, bulky animal wastes such as poultry litter (USEPA 2017b).

The proposed use as a poultry house perimeter spray may result in exposure to honey bee attractive vegetation adjacent to the perimeter wall being sprayed. Therefore perimeter spray applications is considered further for risk estimation. Honey bee RQs were modeled using BeeRex (Version 1.0) using a single maximum application rate of 0.018 lb a.i./A as a foliar spray.

10.2 Bee Risk Characterization

Table 10-1 summarizes the acute and chronic RQ values for adult and larval honey bees. Acute RQs for adult honey bees (contact RQ: 5.5; oral RQ: 39) exceeded the acute LOC (0.4) indicating risk to honey bees on an acute contact and dietary basis. An acute RQ for larval honey bees could not be calculated due to a non-definitive endpoint. However, comparison of the EEC for larvae (0.24 µg a.i./larva) to the non-definitive endpoint (LD_{50}: >0.029 µg a.i./larva; 28% mortality) indicates that the EEC is 8x greater than the non-definitive endpoint. Taken together, the results indicate risks to adult honey bees on an acute basis from perimeter spray use on poultry houses.

Chronic RQs for adult honey bees and larvae, 933 and 3,059 respectively, exceeded the honey bee LOC (1). For adult honey bees, the EEC of 0.57 µg a.i./bee exceeded the adult chronic endpoint (LOAEL: 0.00027 µg a.i./bee) where 30% honey bee mortality occurred. Moreover, for larval honey bees, the EEC of 0.24 µg a.i./larva exceeded the larval chronic endpoint (LOAEL 0.00027 µg a.i./larva) which was based on 18% larval mortality (reduced emergence). Taken together, the results indicate risks to adult and larval honey bees on a chronic basis.

Since the perimeter of the poultry house houses are treated with direct spray, 18 inches up the perimeter wall and 6 inches out from the foundation, and poultry houses are a highly managed landscape and as a result there may be low opportunity for direct spray of blooming vegetation, therefore the conclusions of risk provided here may overestimate the potential exposure to honey bees.

Table 10-1. Estimated Environmental Concentrations (EECs) and Acute and Chronic Risk Quotients (RQs) for Adult and Larval Honey Bees (*Apis mellifera*) from Perimeter Spray Applications to Poultry Houses of Broflanilide using BeeREX (version 1.0)

Life Stage	Description	EEC (µg a.i./bee)	Toxicity Value (µg a.i./bee)	RQ
Poultry house perimeter spray (0.018 lb a.i./A)				
Adult	Acute contact LD_{50}	0.57	0.0088	**5.5**
	Acute oral LD_{50}	0.57	0.0149	**39**
	Chronic oral NOAEL	0.57	0.00062	**933**
Larval	Acute LD_{50}	0.24	>0.029	NC
	Chronic NOAEL	0.24	0.00008	**3059**
Bolded values exceed the LOC for acute risk of 0.4 or the chronic risk LOC of 1.0. The endpoints listed in the table are the endpoint used to calculate the RQ. NC = not calculated due to non-definite endpoint.				

a. *On-Field Risk Evaluation for Other Non-Apis Invertebrates*

Bombus toxicity and risk

Laboratory-based broflanilide toxicity studies were conducted using TGAI (98% a.i.; MRID 50211466) and TEP (9.6% a.i.; MRID 50325608) with the social non-*Apis* bumblebee *Bombus terrestris*. In the contact toxicity tests, the 48-hr LD_{50}s were >0.120 (37% mortality at highest dose, impairment and slow movement at 0.03 ug a.i./bee and greater) and 0.122 µg a.i./bee respectively. These studies also tested the acute oral toxicity of the compounds with bumblebees; 48-hour acute oral LD_{50}s were 0.0195 and 0.0139 µg a.i./bee respectively. These studies indicate that broflanilide is considered highly toxic to adult bumblebees on an acute and contact basis, and the EEC (0.57 µg a.i./bee) from a single application spray application of broflanilide is 4x greater than the contact LD_{50}s and 30x greater than the oral LD_{50}s. These additional results with the bumblebee support the conclusion of risks to bees.

Perimeters of poultry houses are a highly managed landscape and as a result there may be low opportunity for direct spray of blooming vegetation, therefore the conclusions of risk provided here may overestimate the potential exposure to bees.

Other terrestrial invertebrates

EFED conducted an exposure and risk assessment for terrestrial invertebrates following perimeter spray or application of the poultry litter to the field. Since terrestrial invertebrates may consume a wide variety of diet items, this assessment considered the consumption of plant parts (*e.g.*, seeds, fruits, leaves), and arthropods. EPA estimated exposure with T-REX (**Table 10-2**). The best available toxicity data for terrestrial invertebrates is represented by the honey bee data described in **Section 6.2**. Since broflanilide is highly toxic to adult honey bees on an acute exposure basis, acute exposures to adult invertebrates is assumed to be of concern. For acute risks to larvae, the EECs for most dietary items exceed the non-definitive honey bee larval endpoint (LC_{50}: >0.88 mg a.i./kg-diet) for all proposed uses.

For chronic exposure to adults, all diet item EECs exceeded the NOAEC and LOAEC honey bee endpoints for poultry manure applications (at application rates of 0.02 lbs a.i./A and up to 0.125 lbs a.i./A) and poultry house perimeter spray applications (at a single max application rate of 0.018 lbs a.i./A).

Similarly, for chronic exposures to larvae, the NOAEC and LOAEC are exceeded by all dietary EECs following single applications for all uses and application rates. Therefore, EPA concluded that broflanilide poses a risk to terrestrial invertebrates located on application sites.

Table 10-2. Summary of Dietary (mg a.i./kg-diet) EECs for Broflanilide as Food Residues for Terrestrial Invertebrates and Risk Estimations from Poultry Litter and Perimeter Spray Applications.

Food Type	Dietary-Based EEC (mg/kg-diet)	Chronic Adult Invertebrate Ratios[2] NOAEC: 0.018[3] (LOAEC: 0.034 mg a.i./kg-diet)[3]	Chronic Larval Invertebrate Ratios[2] NOAEC: 0.00229[3] (LOAEC: 0.00696 mg a.i./kg-diet)[3]
Poultry litter soil amendment (0.02 lbs a.i./A, 1x)			
Short grass[1]	4.8	267 (141)	2096 (690)
Tall grass[1]	2.2	122 (65)	961 (316)
Broadleaf plants[1]	2.7	150 (79)	1179 (388)
Fruits/pods[1]	0.3	17 (9)	131 (43)
Arthropods[1]	1.9	106 (56)	830 (273)
Seeds (granivore)[1]	4.8	267 (141)	2096 (690)
Poultry litter soil amendment (0.125 lbs a.i./A, 1x)			
Short grass[1]	30	1667 (882)	13100 (4310)
Tall grass[1]	14	778 (412)	6114 (2011)
Broadleaf plants[1]	17	944 (500)	7424 (2443)
Fruits/pods[1]	1.9	106 (56)	830 (273)

Food Type	Dietary-Based EEC (mg/kg-diet)	Chronic Adult Invertebrate Ratios[2] NOAEC: 0.018[3] (LOAEC: 0.034 mg a.i./kg-diet)[3]	Chronic Larval Invertebrate Ratios[2] NOAEC: 0.00229[3] (LOAEC: 0.00696 mg a.i./kg-diet)[3]
Arthropods[1]	12	667 (353)	5240 (1724)
Seeds (granivore)[1]	30	1667 (882)	13100 (4310)
Poultry house perimeter spray (0.018 lbs a.i./A, 1x)			
Short grass[1]	4.3	239 (126)	1878 (618)
Tall grass[1]	2.0	111 (59)	873 (287)
Broadleaf plants[1]	2.4	133 (71)	1048 (345)
Fruits/pods[1]	0.3	17 (9)	131 (43)
Arthropods[1]	1.7	94 (50)	742 (244)
Seeds (granivore)[1]	4.3	239 (126)	1878 (618)

[1] EEC estimated with T-REX v.1.5.2, Upper-Bound Kenaga; see https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#t-rex for model details.
[2] Ratios > 1 indicate that the dietary EEC is greater than the endpoint and there is a potential for risk.
[3]Chronic endpoints for honey bee larva and adults are used as surrogate for larval and adult invertebrates.

11 Terrestrial Plant Risk Assessment

11.1 Terrestrial Plant Exposure Assessment and Characterization

RQs for terrestrial plants could not be calculated due to non-definitive EC_{25} endpoints in the vegetative vigor and seedling emergence studies for dicots and monocots. For monocots, the EC_{25} was >0.091 lb a.i./A in both the vegetative and seedling emergence studies for all species tested. For dicots, the EC_{25} was not considered reliable in the vegetative vigor study and was >0.091 lb a.i./A in the seedling emergence study. The single max application rates for poultry house perimeter spray (0.018 lb a.i./A) and poultry manure field application (0.02, 0.04, and 0.08 lb a.i./A) are below the highest tested concentration in the available studies. Because the proposed application rates are below the concentrations that did not achieve a 25% effect level, risk is presumed low for terrestrial plants.

12 Conclusions

This ERA examines the environmental fate of broflanilide and the potential for adverse effects on non-listed species from exposure associated with proposed uses of broflanilide in and around poultry houses and as a poultry litter amendment to agricultural fields. Given the proposed uses of broflanilide and its environmental fate properties, exposure of non-target terrestrial and/or aquatic organisms is possible. There is a potential for direct adverse effects to terrestrial and aquatic invertebrates, and because of the persistence of broflanilide in sediments these risks are likely to increase with annual reapplications. For spray applications, contact and dietary exposure to bees may occur if attractive vegetation is adjacent to the application area. Additionally, poultry manure application and poultry house spray applications pose a risk to terrestrial invertebrates from dietary items in the treated field, and also pose a chronic risk to birds and mammals following the potential exposure through consumption of broflanilide contaminated aquatic organisms. Available data suggests a low risk potential to birds and mammals from exposure of food sources in the field. Risks to plants, birds, and fish are considered low for the proposed uses.

13 Literature Cited

Armitage, J. M., & Gobas, F. A. P. C. 2007. A terrestrial food-chain bioaccumulation model for POPs. *Environmental Science and Technology, 41*, 4019-4025.

Arnot, J. A., & Gobas, F. A. P. C. 2004. A food web bioaccumulation model for organic chemicals in aquatic ecosystems. *Environmental Toxicology and Chemistry, 23*(10), 2343-2355.

Blomquist, J. D., Denis, J. M., Cowles, J. L., Hetrick, J. A., Jones, R. D., & Birchfield, N. 2001. *Pesticides in Selected Water-Supply Reservoirs and Finished Drinking Water, 1999-2000: Summary of Results from a Pilot Monitoring Program*. Open-File Report 01-456. United States Geological Survey. Available at hthttps://pubs.usgs.gov/of/2001/0456/report.pdf.

CADPR. 2012. Surface Water Protection Program Database. Available at http://www.cdpr.ca.gov/docs/emon/surfwtr/surfdata.htm.

CADPR. 2020. *Department of Pesticide Regulation Surface Water Database*. California Environmental Protection Agency. Database accessed on February 27, 2004, by K. Starner, Environmental Research Scientist, Environmental Monitoring Branch. Available at http://www.cdpr.ca.gov/docs/emon/surfwtr/surfdata.htm.

Cleveland, L., & Hamilton, S. J. 1983. Toxicity of the organophosphorus defoliant DEF to rainbow trout (*Salmo gairdneri*) and channel catfish (*Ictalurus puntatus*). *Aquatic Toxicology, 4*(4), 341-355.

Dierner, J. E. 1986. The ecology and management of the Gopher Tortoise in the Southeastern United States. *Herpetologica, 42*(1), 125-133.

Duke. (2013). Passive Voice in Scientific Writing. Retrieved February 22, 2018, Available at https://cgi.duke.edu/web/sciwriting/index.php?action=passive_voice.

FAO. 2000. Appendix 2. Parameters of pesticides that influence processes in the soil. In FAO Information Division Editorial Group (Ed.), *Pesticide Disposal Series 8. Assessing Soil Contamination. A Reference Manual*. Rome: Food & Agriculture Organization of the United Nations (FAO). Available at http://www.fao.org/DOCREP/003/X2570E/X2570E06.htm

Goring, C. A. I., Laskowski, D. A., Hamaker, J. H., & Meikle, R. W. 1975. Principles of pesticide degradation in soil. In R. Haque & V. H. Freed (Eds.), *Environmental dynamics of* *pesticides.* . NY: Plenum Press. Available at https://link.springer.com/chapter/10.1007%2F978-1-4684-2862-9_9.

Kilimstra, W. D., & Newsome, F. 1960. Some observations on the food coactions on the Common Box Turtle, Terrapene C. Carolina. *Ecology, 41*(4), 639-647.

Mushinsky, H. R., Stilson, T. A., & McCoy, E. R. 2003. Diet and Dietary Preference of the Juvenile Gopher Tortoise (Gopherus polyphemus). *Herpetologica, 59*(4), 475-483.

NAFTA. 2012. *Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media*. December 2012. NAFTA Technical Working Group on Pesticides. Available at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-calculate-representative-half-life-values.

Oregon Department of Environmental Quality. 2015. *Laboratory Analytical Storage and Retrieval Database (LASAR)*. Available at https://oregonexplorer.info/content/oregon-department-environmental-quality-deq-laboratory-analytical-storage-and-retrieval.

SAP. 2009. *SAP Minutes No. 2009-01. A set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Selected Issues Associated with the Risk Assessment Process for Pesticides with Persistent, Bioaccumulative, and Toxic Characteristics. October 28-31, 2008.* January 29, 2009. FIFRA Scientific Advisory Panel. Office of Science Coordination and Policy. Available at https://www.regulations.gov/docketBrowser?rpp=50&po=0&D=EPA-HQ-OPP-2008-0550.

State Water Resources Control Board. 2015. California Environmental Data Exchange Network. California State Water Resources Control Board. Available at http://www.ceden.org/.

USDA. 2013. Pesticide Data Program. U.S. Department of Agriculture. Agricultural Marketing Service. Available at http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateC&navID=&rightNav1=&topNav=&leftNav=ScienceandLaboratories&page=PesticideDataProgram&resultType=&acct=pestcddataprg.

USDA. 2018. *Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen*. Document cites 2017 above the Table of Contents; however, the document was completed in January 2018. U.S. Department of Agriculture. Available at https://www.ars.usda.gov/ARSUserFiles/OPMP/Attractiveness%20of%20Agriculture%20Crops%20to%20Pollinating%20Bees%20Report-FINAL_Web%20Version_Jan%203_2018.pdf.

USEPA. 1993. *Wildlife Exposure Factors Handbook*. EPA/600/R-13/187a. Office of Research and Development. U.S. Environmental Protection Agency. Available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=2799.

USEPA. 2004a. *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs*. Environmental Fate and Effects Division. Office of Pesticide Programs. U.S. Environmental Protection Agency. Available at http://www.epa.gov/espp/consultation/ecorisk-overview.pdf.

USEPA. 2004b. *Government Printing Office. Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs*. January 23, 2004. Environmental Fate and Effects Division. Office of Pesticide Programs. U.S. Environmental Protection Agency. Available at https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf.

USEPA. 2009. *Ecological Risk Assessment for the Section 3 New Uses of Acetamiprid on Red Clover, Small Fruit, and Climbing Vines (Except Kiwi)*. DP364328. Memorandum From B. D. Kiernan & D. Lieu to J. Chao & J. Hebert. December 10, 2009. Environmental Fate and Effects Division. Office of Prevention, Pesticides, and Toxic Substances. United States Environmental Protection Agency.

USEPA. 2009a. *EPA Communications Stylebook: Writing Guide*. U.S. Environmental Protection Agency. Available at https://www.epa.gov/stylebook/epa-communications-stylebook-writing-guide#grammar.

USEPA. 2009b. *Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides, Version 2.1*. Environmental Fate and Effects Division. Office of Pesticide Programs. U.S. Environmental Protection Agency. Available at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-selecting-input-parameters-modeling.

USEPA. 2010a. *Guidance for Reporting on the Environmental Fate and Transport of the Stressors of Concern in the Problem Formulation for Registration Review, Registration Review Risk Assessments, Listed Species Litigation Assessments, New Chemical Risk Assessments, and Other Relevant Risk Assessments*. January 25, 2010. Environmental Fate and Effects Division. Office of Chemical Safety and Pollution Prevention. U.S. Environmental Protection Agency. Available at http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/endangered_species_reregistration_workgroup/esa_reporting_fate.htm.

USEPA. 2010b. *WQTT Advisory Note Number 9: Temperature Adjustments for Aquatic Metabolism Inputs to EXAMs and PE5*. Memorandum From D. F. Young to Water Quality Tech Team. September 21, 2010. Environmental Fate and Effects Division. Office of Chemical Safety and Pollution Prevention. U.S. Environmental Protection Agency.

USEPA. 2011. *Guidance for Using Non-Definitive Endpoints in Evaluating Risks to Listed and Non-listed Animal Species*. Memorandum From D. J. Brady to E. F. a. E. Division. May 10, 2011. Environmental Fate and Effects Division. Office of Chemical Safety and Pollution Prevention. U.S. Environmental Protection Agency. Available at http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/endangered_species_reregistration_workgroup/esa_non_definitive_endpoints.htm.

USEPA. 2012a. *BEAD Chemical Profile for Registration Review: Acetamiprid*. Memorandum From D. Brassard, R. Prierto & M. Ranville to C. Britton. March 1, 2012. Biological and Economic Analysis Division. Office of Pesticide Programs. United States Environmental Protection Agency.

USEPA. 2012b. *Standard Operating Procedure for Using the NAFTA Guidance to Calculate Representative Half-life Values and Characterizing Pesticide Degradation*. November 30, 2012. Environmental Fate and Effects Division. Office of Pesticide Programs. U.S. Environmental Protection Agency. Available at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-calculate-representative-half-life-values.

USEPA. 2012c. *White Paper in Support of the Proposed Risk Assessment Process for Bees. September 11-14, 2012*. September 11, 2012. U.S. Environmental Protection Agency. Pest Management Regulatory Agency. California Department of Pesticide Regulation. Available at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0543-0004.

USEPA. 2013a. *Guidance for Using PRZM-GW in Drinking Water Exposure Assessments*. December 11, 2012. Environmental Fate and Effects Division. Office of Pesticide Programs. U.S. Environmental Protection Agency.

USEPA. 2013b. *Guidance on Modeling Offsite Deposition of Pesticides Via Spray Drift for Ecological and Drinking Water Assessment*. Environmental Fate and Effects Division. Office of Pesticide Programs. Office of Chemical Safety and Pollution Prevention. U.S. Environmental Protection Agency. Available at http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2013-0676.

USEPA. 2014a. *Development of Community Water System Drinking Water Intake Percent Cropped Area Adjustment Factors for use in Drinking Water Exposure Assessments: 2014 Update*. 9/9/14. Environmental Fate and Effects Division. Office of Chemical Safety and Pollution Prevention. U.S. Environmental Protection Agency. Available at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/development-community-water-system-drinking-water.

USEPA. 2014b. *Guidance for Addressing Unextracted Residues in Laboratory Studies*. Memorandum From to E. F. a. E. Division. September 12, 2014. Environmental Fate and

Effects Division. Office of Pesticide Programs. Office of Chemical Safety and Pollution Prevention. Available at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-addressing-unextracted-pesticide-residues.

USEPA. 2015. *Storet/WQX Data Warehouse*. United States Environmental Protectin Agency. Available at http://www.epa.gov/storet/dw_home.html.

USEPA. 2016. *Refinements for Risk Assessment of Pesticide Treated Seeds - Interim Guidance*. March 31, 2016. Environmental Fate and Effects Division. Office of Pesticide Progams. U.S. Environmental Protection Agency. Available at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/refinements-risk-assessment-pesticide-treated-seeds.

USEPA. 2017. *Guidance for Using Daily Average Aquatic Concentrations in Ecological and Drinking Water Assessments*. June 27, 2017. Environmental Fate and Effects Division. Office of Chemical Safety and Pollution Prevention. U.S. Environmental Protection Agency.

USEPA. 2017b. Clothianidin – Drinking Water Exposure Assessment for Registration Review of All Registered Uses. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division, July 17, 2017.

USEPA. 2019. Thiamethoxam: Drinking Water Exposure Assessment for the Proposed Poultry House Use and Subsequent Poultry Litter Application to Agricultural Fields Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division, May 13, 2019.

USEPA. 2020. Broflanilide: Ecological Risk Assessment for the Proposed Section 3 New Chemical Registration. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division, October 27, 2020.

USEPA, Health Canada PMRA, & California Department of Pesticide Regulation. 2014. *Guidance for Assessing Pesticide Risks to Bees*. June 23, 2014. U.S. Environmental Protection Agency. Health Canada Pest Management Regulatory Agency. California Department of Pesticide Regulation. Available at http://www2.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance.

USEPA, USGS, & NWQMC. 2018. Water Quality Portal. United States Environmental Protection Agency. United States Geological Survey. National Water Quality Monitoring Council. Available at https://www.waterqualitydata.us/.

USGS. 2015. National Water-Quality Assessment Program (NAWQA). U.S. Geological Survey. Available at http://water.usgs.gov/nawqa/.

USGSA. 2011. *Federal Plain Language Guidelines*. March 2011. U. S. General Services Administration. Available at https://plainlanguage.gov/media/FederalPLGuidelines.pdf.

Vitosch, M.L.; J.W. Johnson; and D.B. Mengel. 1995. Tri-State Fertilizer Recommendations for Corn, Soybeans, Wheat *and Alfalfa*. Extension Bulletin E-2567 (New), July 1995. Michigan State University, Lansing, MI.

Washington State Department of Ecology. 2015. *State of Washington Department of Ecology Environmental Monitoring Data*. Washington State Department of Ecology. Available at http://www.ecy.wa.gov/eim/index.htm.

14 Referenced MRIDs

14.1 Environmental Fate Studies

50211433 Kitamura, K. (2017) Soil Adsorption Coefficient of DM-8007: Final Report. Project Number: 2017/7008905, 522/15/K/1611, 652/15/P/4491. Unpublished study prepared by Chemicals Evaluation and Research Institute. 9p.

50211434 Kitamura, K. (2017) Soil Adsorption Coefficient of S(PEP-OH)-8007: Final Report. Project Number: 2017/7008906, 522/15/K/1612, 652/15/P/4494. Unpublished study prepared by Chemicals Evaluation and Research Institute. 9p.

50211435 Miner, P. (2017) Adsorption/Desorption of Carbon-14 DC-DM-8007 in US Soils. Project Number: 034583/1, 034583, 2017/7008697. Unpublished study prepared by Ricerca Biosciences, LLC. 137p.

50211436 Miner, P. (2017) Adsorption/Desorption of Carbon-14 DC-8007 in US Soils. Project Number: 034809, 034809/1, 2017/7016121. Unpublished study prepared by Ricerca Biosciences, LLC. 149p.

50211328 Schick, M. (2016) Hydrolysis of [Carbon 14]MCI-8007 at pH 4, 7 and 9. Project Number: 2499W, 2499W/1, 2016/7012757. Unpublished study prepared by PTRL West, Inc. 54p.

50211329 Ponte, M. (2017) Direct Aqueous Photodegradation of [Carbon 14]MCI-8007: Final Report. Project Number: 2579W, 2579W/2, 2017/7016803. Unpublished study prepared by EAG Laboratories. 215p.

50211330 Ponte, V. (2017) Direct Aqueous Photodegradation of [Carbon 14]Broflanilide in pH 5 and pH 9 Buffer. Project Number: 2914W, 2914W/1, 2017/7016650. Unpublished study prepared by EAG Laboratories. 359p.

50211640 Warren, R. (2017) Atmospheric Degradation of Broflanilide (BAS 450 I or MCI- 8007) by Reaction with the Hydroxyl Radicals and Ozone: Structure-Activity Relationship Calculations Using AOPWIN v1.92: Final Report. Project Number: 439540, 2017/7015636. Unpublished study prepared by BASF Corporation. 13p.

50211427 Strobush, A. ; Ta, C. (2017) Aerobic Soil Metabolism of Carbon-14 Broflanilide (MCI-8007 or BAS 450 I): Final Report. Project Number: 2017/7008279, 818049. Unpublished study prepared by BASF Crop Protection, Agvise Laboratories, Inc. 179p.

50211430 Ta, C. ; Strobush, A. (2017) Aerobic Soil Metabolism of Carbon-14 Broflanilide (MCI-8007 or BAS 450 I) in Intact Soil Cores and Processed Soils: Final Report. Project Number: 780122, 2017/7000457, 2015/7001365. Unpublished study prepared by BASF Corporation. 313p.

50211560 Talken, C. (2017) 450 I (Broflanilide): Outdoor Aerobic Soil Metabolism of Carbon-14-BAS 450 I on Bare Soil in California and Georgia, USA: Final Report. Project Number: 2015/7001365, 725271, 81084. Unpublished study prepared by ABC Laboratories, Inc., Research for Hire, Eurofins Agrosciences, Inc., AGVISE Laboratories. 380p.

50211428 Ta, C.; Alicea, A. ; Graves, C. (2017) Anaerobic Soil Metabolism of Carbon-14 Broflanilide (MCI-8007 or BAS 450 I): Final Report. Project Number: 818051, 2017/7008280, SANCO/10058/2005. Unpublished study prepared by BASF Corporation, Agvise Laboratories, Inc. 201p.

50680701 Ta, C. (2018) Responses of BASF to PMRA on the Identification and Quantification of Broflanilide and Transformation Products from the Chromatograms Provided in PMRA # 2828282, "Anaerobic Soil Metabolism of [Carbon 14] Broflanilide (MCI-8007 or BAS 450 I)". Project Number: 2018/7006697. Unpublished study prepared by BASF Corporation. 30p.

50211437 Stenzel, J.; Schaefer, E. (2017) Aerobic Aquatic Metabolism of Carbon-14 Broflanilide, Also known as Carbon-14 MCI-8007 and Carbon-14 BAS 450 I, in Two Test Systems: Final Report. Project Number: 236E/102, 2017/7016172. Unpublished study prepared by EAG Laboratories. 261p.

50211431 Warren, R.; Gordon, B.; Mitchell, J.; et al. (2017) Terrestrial Field Dissipation of the Insecticide Broflanilide (BAS 450 I or MCI-8007) Following Broadcast Applications of BAS 450 00 I (SC): Final Report. Project Number: 227/32, 710464, 2017/7008695. Unpublished study prepared by BASF Corporation, Ag Systems Associates, Florida Pesticide Research, Inc., California Agricultural Research, Inc., Qualls Agricultural Laboratory, Northern Plains Ag Research, Inc., Agvise Laboratories, Inc., Primera Analytical Solutions Corp. 1141p.

50211559 Gordon, B. (2017) Freezer Storage Stability of BAS 450 I and its Relevant Metabolites DM-8007, DC-DM-8007, DC-8007 and S(PFP-OH)-8007 in Soil. Project Number: 414635, 2017/7012475, 710464. Unpublished study prepared by BASF Corporation. 339p.

50211560 Talken, C. (2017) 450 I (Broflanilide): Outdoor Aerobic Soil Metabolism of Carbon-14-BAS 450 I on Bare Soil in California and Georgia, USA: Final Report. Project Number: 2015/7001365, 725271, 81084. Unpublished study prepared by ABC Laboratories, Inc., Research for Hire, Eurofins Agrosciences, Inc., AGVISE Laboratories. 380p.

50124721 Altenburg, M. (2017) Potential effects of BAS 450 01 I on the reproduction of the soil mites Hypoaspis aculeifer in artificial soil with 5% peat: Final Report. Project Number: 788193, 2017/1000741. Unpublished study prepared by BASF SE. 33p.

50211451 Dodd, E. (2016) Mel-8007 (BAS 450 I, Broflanilide): Bioconcentration study in the Rainbow Trout (Oncorhynchus mykiss): Final Report. Project Number: MUY0012, 2017/7008732. Unpublished study prepared by Envigo CRS Limited. 135p.

50211562 Kendall, T.; Krueger, H.; Thomas, S. (2012) A Flow-Through Bioconcentration Screening Test with the Rainbow Trout (Oncorhynchus mykiss) Using Carbon-14-MLP-9595 and Carbon-14-MLP-8607: Final Report. Project Number: 236A/137, 2012/7008465, NP153819. Unpublished study prepared by Wildlife International Ltd. 41p.

50211340 Delinsky, D. (2017) Validation of Method D1603/01: Method for the Determination of Residues of BAS 450 I and its Metabolites DM-8007, DC-DM- 8007, DC-8007 and S(PFP-OH)-8007 in Soil by LC-MS/MS (at LOQ of 1 ppb): Final Report. Project Number: 815843, 2017/7001823. Unpublished study prepared by BASF Corporation. 184p.

50211341 Delinsky, D. (2017) Validation of Method D1608/01: Method for the Determination of BAS 450 I and its Metabolites DM-8007, DC-DM-8007 and S(PFP-OH)-8007 in Surface and Drinking Water by LC-MS/MS: Final Report. Project Number: 725931, 2017/7000331. Unpublished study prepared by BASF Corporation. 198p.

50211477 Mack, P. (2017) Determination of Residues of BAS 450 00 I in Pollen of Corn after One In-Furrow Soil Application in a Filed Residue Study in Germany 2016: Final Report. Project Number: 773951/1, S16/02197, 2016/1222128. Unpublished study prepared by Eurofins Agroscience Services EcoChem GmbH. 177p.

50211478 Mack, P. (2017) Determination of Residues in Pollen and Nectar of Oilseed Rape Grown as a Succeeding Crop in Corn Field Previously Treated Once with BAS 450 00 I as a Soil In-Furrow Application: Final Report. Project Number: 773951/2, S16/00561, 2016/1222129. Unpublished study prepared by Eurofins Agroscience Services EcoChem GmbH. 217p.

50211556 Delinsky, D. (2017) Validation of Method D1705/01: Method for the Determination of S(Br-OH)-8007 (Reg, No. 5959595), AB-Oxa (Reg. No. 5959600), and MFBA (Reg. No. 6088668) in Surface and Drinking Water by LC-MS/MS: Final Report. Project Number: 838397, 2017/7012333. Unpublished study prepared by BASF Crop Protection. 141p.

50211645 Delinsky, D. (2017) Evaluation of the Limit Detection (LOD) for Method D1603/01, "Method for the Determination of Residue of BAS 450 I and its Metabolites DM-8007, DC-DM-8007, DC-8007 and S(PFP-OH)-8007 in Soil by LC- MS/MS (at LOQ of 1ppb): Final Report. Project Number: 834706, 2017/7008794. Unpublished study prepared by BASF Corporation. 42p.

50211646 Neeley, M. (2017) Independent Laboratory Validation of the following Method Entitled: BASF Analytical Method D1603/01: "Method for the Determination of Residues of BAS 450 I and its Metabolites DM-8007, DC-DM-8007, DC-8007 and S(PFP-OH)-8007 in Soil by LC-MS/MS (at LOQ of 1ppb)": Amended Final Report. Project Number: 776691, 16/CPS/052, 2017/7016080. Unpublished study prepared by Critical Path Services, LLC (CPS). 135p.

50211647 Horowitz, M. (2017) Evaluation of the Limit of Detection (LOD) for Method D1608/01: "Method for the Determination of BAS 450 I and its Metabolites DM-8007, DC-DM-8007, DC-8007 and S(PFP-OH)-8007 in Surface and Drinking Water by LC-MS/MS": Final Report. Project Number: 834707, 2017/7008773. Unpublished study prepared by BASF Corporation. 48p.

50211648 Xu, A. (2017) Independent Laboratory Validation of Method D1608/01: "Method for the Determination of BAS 450 I and its Metabolites DM-8007, DC-DM-8007, DC-8007 and S9PFP-OH)-8007 in Surface and Drinking Water by LC-MS/MS: Amended Final Report. Project Number: 776692, 053/1651, PASC/REP/0986. Unpublished study prepared by Primera Analytical Solutions Corporation. 161p.

50211649 Delinsky, D. (2017) Evaluation of Limit of Detection (LOD) for Method D1705/01, "Method for the Determination of S(BR-OH)-8007, AB-Oxa, and MFBA in Surface and Drinking Water by LC-MS/MS": Final Report. Project Number: 838399, 2017/7008790. Unpublished study prepared by BASF Corporation. 37p.

50211650 Xu, A. (2017) Independent Laboratory Validation of "Method for the Determination of S(Br-OH)-8007, AB-Oxa, and MFBA in Surface and Drinking Water by LC-MS/MS". Project Number: 2017/7012334. Unpublished study prepared by Primera Analytical Solutions Corporation. 159p.

14.2 Ecological Effects Studies

50211452 Brougher, D.; Oliver, D.; Gallagher, S. (2016) MCI-8007 (BAS 450 I): A 48-Hour Static-Renewal Acute Toxicity Test with the Cladoceran (Daphnia magna): Final Report. Project Number: 236A/171, 706453, 2016/7011589. Unpublished study prepared by EAG Laboratories. 57p.

50211514 Yamaguchi, N. (2016) Acute Immobilization Test of MFBA with Daphnia magna. Project Number: A160093, 2016/7012502. Unpublished study prepared by LSI Medience Corporation. 38p.

50211563 Yoshimura, N. (2016) Reproduction Test of MFBA with Daphnia magna. Project Number: A160094, 2016/7012501. Unpublished study prepared by LSI Medience Corporation. 59p.

50211485 Claude, M.; Oliver, D.; Gallagher, S. (2016) BAS 450 I: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysis (Americamysis bahia). Project Number: 147A/306B, 706461, 2016/7001699. Unpublished study prepared by Wildlife International, Ltd. 76p.

50211486 Mason, J. (2017) BAS 450 I - Acute Toxicity Test with Eastern Oyster (Crassostrea virginica) Under Flow-Through Conditions: Final Report. Project Number: 986/6304, 838874, 2017/7008755. Unpublished study prepared by Smithers Viscient Laboratories. 60p.

50211485 Claude, M.; Oliver, D.; Gallagher, S. (2016) BAS 450 I: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysis (Americamysis bahia). Project Number: 147A/306B, 706461, 2016/7001699. Unpublished study prepared by Wildlife International, Ltd. 76p.

50211566 Brougher, D.; Lockard, L.; Martin, K.; et al. (2017) BAS 450 I METABOLITE (S(Br-OH)-8007): A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysid (Americamysis bahia): Final Report. Project Number: 147A/333C, 838289, 2017/7016554. Unpublished study prepared by EAG, Inc. 65p.

50211567 Brougher, D.; Oliver, D.; VanHoven, R.; et al. (2017) BAS 450 I METABOLITE (AB-oxa): A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysid (Americamysis bahia): Final Report. Project Number: 147A/334A, 838290, 2017/7016553. Unpublished study prepared by EAG, Inc. 65p.

50211485 Claude, M.; Oliver, D.; Gallagher, S. (2016) BAS 450 I: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysis (Americamysis bahia). Project Number: 147A/306B, 706461, 2016/7001699. Unpublished study prepared by Wildlife International, Ltd. 76p.

50211485 Claude, M.; Oliver, D.; Gallagher, S. (2016) BAS 450 I: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysis (Americamysis bahia). Project Number: 147A/306B, 706461, 2016/7001699. Unpublished study prepared by Wildlife International, Ltd. 76p.

50211446 Milligan, A.; Oliver, D.; Gallagher, S. (2016) MCI-8007 Technical (Broflanilide): A 96-Hour Static-Renewal Acute Toxicity Test with the Rainbow Trout (Oncorhynchus mykiss): Final Report. Project Number: 236A/168, 2016/7011895, 236/04201/RBT/96H3/OECD/OPPTS/100P/628. Unpublished study prepared by EAG Laboratories. 62p.

50211447 Milligan, A.; Oliver, D.; Gallagher, S. (2016) MCI-8007 Technical (Broflanilide): A 96-Hour Static-Renewal Acute Toxicity Test with the Bluegill (Lepomis macrochirus): Final Report. Project Number: 236A/167, 2016/7011894, 236/042016A/BLU/96H3/OECD/OPPTS/100P/616. Unpublished study prepared by EAG Laboratories. 62p.

50211448 Minderhout, T.; Oliver, D.; Gallagher, S. (2016) BAS 450 I: A 96-Hour Flow- Through Toxicity Test with the Fathead Minnow (Pimephales promelas). Project Number: 147A/326, 706458, 2016/7010896. Unpublished study prepared by EAG Laboratories. 59p.

50211485 Claude, M.; Oliver, D.; Gallagher, S. (2016) BAS 450 I: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysis (Americamysis bahia). Project Number: 147A/306B, 706461, 2016/7001699. Unpublished study prepared by Wildlife International, Ltd. 76p.

50211490 Claude, M.; Oliver, D.; Gallagher, S. (2016) BAS 450 I: A 96-Hour Flow-Through Acute Toxicity Test with the Sheepshead Minnow (Cyprinodon variegatus). Project Number: 147A/307, 706460, 2016/7004280. Unpublished study prepared by EAG Laboratories. 60p.

50211512 Milligan, A.; Oliver, D.; Gallagher, S. (2017) MCI-8007 Technical (Broflanilide): A 96-Hour Static-Renewal Acute Toxicity Test with the Common Carp (Cyprinus carpio): Final Report. Project Number: 236A/169, 2017/7016189, 236/042016/CC/96H3/OECD/OPPTS/100P/641. Unpublished study prepared by EAG Laboratories. 65p.

50211453 Vlechev, S.; Janson, G. (2017) Chronic Toxicity of BAS 450 I (MCI-8007) to Daphnia magna STRAUS in a 21 Days Semi-Static Test: Final Report. Project Number: 706454, 2015/1003902. Unpublished study prepared by BASF SE. 68p.

50211488 Claude, M.; Okiver, D.; Gallagher, S. (2017) BAS 450 I: A Flow-Through Life-Cycle Toxicity Test with the Saltwater Mysid (Americamysis bahia): Final Report. Project Number: 147A/309A, 706462, 2017/7012232. Unpublished study prepared by EGA Laboratories. 139p.

50211449 Minderhout, T.; Oliver, D.; Gallagher, S. (2017) BAS 450 I: An Early Life-Stage Toxicity Test with the Fathead Minnow (Pimephales promelas). Project Number: 147A/330, 706459, 2017/7008344. Unpublshed study prepared by EAG Laboratories. 107p.

50211450 Minderhout, T.; Oliver, D.; Gallagher, S. (2017) BAS 450 I: An Early Life-Stage Toxicity Test with the Sheepshead Minnow (Cyprinodon variegatus). Project Number: 147A/310B, 741406, 2017/7000425. Unpublished study prepared by EAG Laboratoreis. 103p.

50211439 Taylor, K. (2016) Northern Bobwhite (Colinus virginianus) Acute Oral Toxicity Test (LD50) with BAS 450 I. Project Number: 706466, 2016/7004181, 986/4122. Unpublished study prepared by Smithers Viscient. 70p.

50211440 Keller, J.; Groters, S.; Ravenzwaay, B. (2015) BAS 450I: Acute Toxicity in the Mallard Duck (Anas platyrhynchos) after Single Oral Administration (LD50). Project Number: 13W0219/10W019, 706469, 2015/1099658. Unpublished study prepared by BASF SE. 66p.

50211441 Keller, J.; Groeters, S.; Ravenzwaay, B. (2015) BAS 450I: Acute Toxicity in the Canary (Serinus canaria) after Single Oral Administration (LD50). Project Number: 15W0219/10W018, 738719, 2015/1095047. Unpublished study prepared by BASF SE. 68p.

50211442 Martin, K.; Temple, D.; Keller, K.; et al. (2017) BAS 450 I (MCI-8007): A Dietary LC50 Study with the Mallard. Project Number: 147B/312, 706470, 2017/7007306. Unpublished study prepared by EAG Laboratories. 68p.

50211443 Hubbard, P.; Temple, D.; Keller, K.; et al. (2017) BAS 450 I (MCI-8007): A Dietary LC50 Study with the Northern Bobwhite. Project Number: 147B/311, 706467, 2017/7007305. Unpublished study prepared by EAG Laboratories. 70p.

50211444 Wikander, M.; Temple, D.; Martin, K.; et al. (2017) BAS 450 I (MCI-8007): A Reproduction Study with the Mallard: Final Report. Project Number: 147B/285, 706471, 2017/7012416. Unpublished study prepared by EAG, Inc. 291p.

50211445 Martin, K.; Bryden, M.; Lockard, L.; et al. (2016) BAS 450 I (MCI-8007): A Reproduction Study with the Northern Bobwhite. Project Number: 147B/281, 744218, 2016/7001783. Unpublished study prepared by Wildlife International Ltd. 254p.

50211561 Martin, K.; Elliott, S.; Temple, D.; et al. (2017) BAS 450 I (MCI-8007): A Reproduction Study with the Mallard: Final Report. Project Number: 147B/327, 823204, 2017/7012417. Unpublished study prepared by EAG, Inc. 300p.

49722101 Ruhland, S. (2015) Chronic Toxicity of BAS 450 I (MCI-8007) to the Honeybee (Apis mellifera L.) under Laboratory Conditions. Project Number: 2015/1243703, 728743, 15/10/48/035/B. Unpublished study prepared by BioChem agrar Labor fuer biologische und chemische Analytik GmbH. 15p.

49722102 Kleebaum, K. (2015) Chronic Toxicity of BAS 450 I (MCI-8007) to Honeybee Larvae Apis mellifera L. under Laboratory Conditions (in vitro). Project Number: 728744, 2015/1243704, 15/10/48/098/B. Unpublished study prepared by BioChem agrar Labor fuer biologische und chemische Analytik GmbH. 18p.

50124717 Franke, M. (2016) Acute toxicity of BAS 450 01 I to the honeybee Apis mellifera L. under laboratory conditions: Final Report. Project Number: 803700, 16/10/48/151/B, 2016/1193024. Unpublished study prepared by Biochem Agrar, Labor fuer Biologische und Chemische. 42p.

50211465 Franke, M. (2015) Acute Toxicity of MCI-8700 (BAS 450 I) to the Honeybee Apis mellifera L. under Laboratory conditions: Final Report. Project Number: 706472, 15/10/48/096/B, 2015/7008312. Unpublished study prepared by Biochem Agrar, Labor fuer Biologische und Chemische. 45p.

50211565 Kling, A. (2017) Metabolite of BAS 450 I - Acute Oral and Contact Toxicity to the Honey Bee, Apis mellifera L. under Laboratory Conditions: Final Report. Project Number: 809888, S17/02982, 2017/1064904. Unpublished study prepared by Eurofins Agroscience Services EcoChem GmbH/Ecotox GmbH. 37p.

50325607 Franke, M. (2017) Acute Toxicity of BAS 450 00 I to the Honeybee Apis melifera L. under Laboratory Conditions (Including Amendment No. 1): Final Report. Project Number: 706784, 15/10/48/095/B, 2017/7016518. Unpublished study prepared by Biochem Agrar. 46p.

50211470 Bergfiled, A. (2015) BAS 450 00 I (a.i. Reg. No. 5672774): Toxicity of Residues on Foliage to the Honey Bee, Apis mellifera. Project Number: 81147, 727107, 2014/7003659. Unpublished study prepared by ABC Laboratories, Inc. 87p.

50325617 McKelvey, R.; Porch, J.; Siddiqui, A. (2017) BAS 450 00 I: A Toxicity Test to Determine the Effects on Seedling Emergence and Seedling Growth of Ten Species of Plants: Final Report. Project Number: 147P/116, 706781, 2017/7000508. Unpublished study prepared by EAG Laboratories-Easton. 114p.

50325616 Orvos, A.; Porch, J.; Elliott, S. (2016) BAS 450 00 I: A Toxicity Test to Determine the Effects on Vegetative Vigor of Ten Species of Plants. Project Number: 147P/117, 706782, 2016/7006296. Unpublished study prepared by Wildlife International, Ltd. 118p.

50325617 McKelvey, R.; Porch, J.; Siddiqui, A. (2017) BAS 450 00 I: A Toxicity Test to Determine the Effects on Seedling Emergence and Seedling Growth of Ten Species of Plants: Final Report. Project Number: 147P/116, 706781, 2017/7000508. Unpublished study prepared by EAG Laboratories-Easton. 114p.

50325616 Orvos, A.; Porch, J.; Elliott, S. (2016) BAS 450 00 I: A Toxicity Test to Determine the Effects on Vegetative Vigor of Ten Species of Plants. Project Number: 147P/117, 706782, 2016/7006296. Unpublished study prepared by Wildlife International, Ltd. 118p.

50211464 Arnie, J.; Oliver, D.; Porch, J.; et al. (2016) BAS 450 I: A 7-Day Static-Renewal Toxicity Test with Duckweed (Lemna gibba G3). Project Number: 147P/120A, 706452, 2016/7009370. Unpublished study prepared by Wildlife International, Ltd. 72p.

50211455 Arnie, J.; Oliver, D.; Porch, J.; et al. (2017) MCI-8007 (Broflanilide): A 96-Hour Toxicity Test with the Freshwater Alga (Raphidocelis subcapitata): Final Report. Project Number: 236P/108, 2017/7015494, 236/101716B/RAPHIDO/96/OECD/OCSPP/100P/621. Unpublished study prepared by EAG Laboratories. 73p.

50211456 Arnie, J.; Oliver, D.; Porch, J.; et al. (2016) BAS 450 I: A 96-Hour Toxicity Test with the Cyanobacteria (Anabaena flos-aquae). Project Number: 147P/118A/BASF/STUDY, 706451, 2016/7005685. Unpublished study prepared by Wildlife International, Ltd. 69p.

50211457 Arnie, J.; Oliver, D.; Proch, J.; et al. (2016) BAS 450 I: A 96-Hour Toxicity Test with the Freshwater Diatom (Navicula pelliculosa). Project Number: 147P/119A, 706479, 2016/7005686. Unpublished study prepared by Wildlife International, Ltd. 74p.

50211458 Arnie, J.; Oliver, D.; Porch, J.; et al. (2016) BAS 450 I: A 96-Hour Toxicity Test with the Marine Diatom (Skeletonema costatum). Project Number: 147P/114B/BASF, 706464, 2016/7005684. Unpublished study prepared by EAG Laboratories. 75p.

50905101 Arnie, J.; Paz, T.; Tull, C.; et al. (2019) Broflanilide Metabolite DC-8007: A 96 - Hour Toxicity Test with the Freshwater Alga (Raphidocelis subcapitata): Final Report. Project Number: 236P/111, 2019/2045045. Unpublished study prepared by EAG Laboratories. 74p.

50211454 Arnie, J.; Oliver, D.; Porch, J.; et al. (2017) MCI-8007 (Broflanilide): A 72-Hour Toxicity Test with the Freshwater Alga (Pseudokirchneriella subcapitata): Final Report. Project Number: 236P/105, 2017/7012409, 236/042016A/PSEUDO72/OECD/SUB236. Unpublished study preapred by EAG Laboratories. 63p.

50211455 Arnie, J.; Oliver, D.; Porch, J.; et al. (2017) MCI-8007 (Broflanilide): A 96-Hour Toxicity Test with the Freshwater Alga (Raphidocelis subcapitata): Final Report. Project Number: 236P/108, 2017/7015494, 236/101716B/RAPHIDO/96/OECD/OCSPP/100P/621. Unpublished study prepared by EAG Laboratories. 73p.

50211456 Arnie, J.; Oliver, D.; Porch, J.; et al. (2016) BAS 450 I: A 96-Hour Toxicity Test with the Cyanobacteria (Anabaena flos-aquae). Project Number: 147P/118A/BASF/STUDY, 706451, 2016/7005685. Unpublished study prepared by Wildlife International, Ltd. 69p.

50211457 Arnie, J.; Oliver, D.; Proch, J.; et al. (2016) BAS 450 I: A 96-Hour Toxicity Test with the Freshwater Diatom (Navicula pelliculosa). Project Number: 147P/119A, 706479, 2016/7005686. Unpublished study prepared by Wildlife International, Ltd. 74p.

50211564 Yamaguchi, N. (2016) Growth Inhibition Test of MFBA with Green Algae (Pseudokirchneriella subcapitata). Project Number: A160092, 2016/7012524. Unpublished study prepared by LSI Medience Corporation. 41p.

50973901 (50211568) Brougher, D.; Lockard, L.; Gallagher, S.; et al. (2017) BAS 450 I Metabolite (MFBA): A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysid (Americamysis bahia): Final Report. Project Number: 147A/335, 839217, 2017/7016207. Unpublished study prepared by EAG, Inc. 59p.

51780501 Henry, E.; Mullen, K. (2021) Treviar SC Insecticide: Use of Poultry Litter as an Agricultural Fertilizer: Final Report. Project Number: 2021/2040455. Unpublished study prepared by BASF Corporation. 11p.

51780502 Strobush, A.; Ta, C. (2020) Metabolism of C-Broflanilide (MCI-8007 or BAS 450 I) in Poultry Litter (Non GLP): Final Report. Project Number: 2020/2003274, 870047. Unpublished study prepared by BASF Corporation and Agvise Laboratories, Inc. 95p.

51780503 Strobush, A.; Ta, C. (2020) Absorption and Bioavailability of 14C-Broflanilide (MCI-8007 or BAS 450 I) in Poultry Litter and Soil Amended with Used Litter (Non GLP): Final Report. Project Number: 2020/2103980, 870047. Unpublished study prepared by BASF Corporation and Agvise Laboratories, Inc. 51p.

51780504 Donaldson, F.; Henry, E.; Ta, C.; et al. (2021) Bioavailability of Broflanilide (BAS 450 I) Applied to Poultry Litter and Soil: Final Report. Project Number: 2020/2089770. Unpublished study prepared by BASF Corporation. 19p.

Appendix A. Application Rate Derivation, Example Aquatic Modeling Output and Input Batch File

A.1. Application Rate Derivation: Indoor Use in Poultry Houses

Single application rate (per acre) = (0.834 lbs a.i./128 fl oz) * (1.25 fl oz/1 gallon) * (1 gallon/ 1000 ft^2) * (43,560 ft^2/acre) = 0.355 lbs a.i./acre

Where

- One gallon (128 fl oz) contains 0.834 lbs broflanilide (Treviar™ SC label)
- 1.25 fl oz of Treviar SC to prepare 1 gallon of 0.1% dilute solution (Treviar™ SC label)
- 1 gallon of 0.1 % dilute solution recommended to treat 1000 ft^2 indoor and outdoor uses (Treviar™ SC label).

Annual application rate: 0.355 lbs a.i./A X 2 applications per year = 0.71 lbs a.i./A/year

A.2. Application Rate Derivation: Treatment of Poultry (Broiler) Houses

For the proposed poultry house use, the chicken litter collected from the broiler house could potentially be used as a soil amendment after it has been treated with broflanilide. To assess the impacts of poultry litter use as a soil amendment, EFED modeled the amount of broflanilide predicted to be in the poultry litter and theoretically applied it to a corn field prior to planting. The primary pest targeted by this use is the darkling beetle, which is mostly found on the perimeter portions of floors and lower walls, near feeders and water lines. According to the proposed label, there is a restriction of not making more than two whole-house indoor applications per year no less than 7 weeks apart. This label direction would cap the maximum yearly application rate to 0.7 lbs a.i./A/yr. Based on the proposed label, this assessment assumes 2 flocks of broilers can be raised based on the 7-week retreatment interval before a whole house litter clean out.

A field application rate for broflanilide-treated manure on a corn field was developed using the following process. Equation references can be found at USEPA, 2012; DP 402250+. The following is an example calculation using the maximum yearly application rate of 0.7 lbs a.i./A/year and a litter application rate of 12.5 tons/A.

a. Per the proposed label directions, this assessment is assuming two flocks of broilers before a full litter clean out, followed by storage, then application on a corn field. Two flocks may produce 56 tons of manure, and require 11.7 tons of bedding, resulting in a total of 68 tons of litter.
b. The cumulative residual concentration of broflanilide in litter is 0.71 lbs a.i./68 tons litter = 0.01 lbs a.i./ton litter.
c. The maximum elemental nitrogen requirement for corn is 220 lb plant available nitrogen per acre (N/A). This requirement can vary. The average nitrogen requirement

for corn is 140 lb plant available N/A. So, multiple litter application rates were modeled to bracket nitrogen loading in this assessment (see **Table A-1**).

d. Two flocks of broilers produce 4800 lb nitrogen; 45% of this is assumed/estimated to be lost during storage, resulting in 2640 lbs of nitrogen.
e. Only 90% of the nitrogen is available to plants in the first year (USDA, 1992; estimate of mineralization), resulting in 2376 lbs of plant available nitrogen.
f. An additional 50% of the nitrogen is lost during application, resulting in 1188 lbs plant-available nitrogen applied to the field.
g. Based on the nitrogen application rate of 220 lb N/A (Vitosch, *et al.*, 1995), this results in 5.4 acres being treated with the manure from two flocks (1188 lbs N / 220 lbs N/A = 5.4 A).
h. Based on a cumulative broiler litter production of 203 tons, this results in a litter application rate of 12.5 tons/A (68 tons litter /5.4 A = 12.5 tons litter/A).
i. Based on a residual broflanilide concentration in litter of 0.01 lbs a.i./ton litter, and a litter application rate of 12.5 tons/A, the outdoor equivalent application rate for broflanilide is 0.125 lbs a.i./A.

A lower-bound application rate for broflanilide-treated poultry litter for corn was estimated using the process described above except with a lower application rate of litter per acre. Poultry manure application rate information collected by the Biological and Economic Analysis Division (BEAD; USEPA 2017d) suggests that growers would rarely use more than 2-3 tons of litter per acre. This is due both to practicality (transportation costs, bulk handling, *etc.*) and the legal limits imposed by state nutrient management regulations, which are largely driven by phosphorous rather than nitrogen. (*i.e.*, phosphorous is limiting and precludes the high tonnage usage of manure for corn production). Therefore, based on a residual broflanilide concentration in litter of 0.01 lbs a.i./ton litter, and a typical manure application rate of 2.0 tons/A, the lower-bound outdoor equivalent application rate for broflanilide is 0.02 lbs a.i./A (*i.e.*, 0.01 lbs a.i./ton * 2.0 tons/A).

Since the broflanilide application rate can vary by the nitrogen requirement of the crop (mass applied as litter application), multiple scenarios were modeled to hypothetically characterize poultry litter application to agricultural fields. **Table A-1** is a matrix of field application rates modeled in this assessment.

Table A-1. Broflanilide Field Application Rates (lb a.i./A)

Litter Treatment[1] (tons/A)	Field Application Rate (lb. a.i./A)	Field Application Rate (kg/ha)
2.0	0.020	0.022
4.0	0.040	0.045
8.0 (avg. N)	0.080	0.090
12.5 (max. N)	0.125	0.140

A.3. Application Rate Derivation: Exterior Perimeter Treatment of Poultry Houses

Note: Application rate for perimeter treatments needs to be adjusted for the perimeter size.

Labeled single application rate (per acre) = (0.834 lbs a.i./128 fl oz) * (1.25 fl oz/1 gallon) * (1 gallon/ 1000 ft^2) * (43,560 ft^2/acre) = 0.355 lbs a.i./acre

Where

- One gallon (128 fl oz) contains 0.834 lbs broflanilide (Treviar™ SC label)
- 1.25 fl oz of Treviar SC to prepare 1 gallon of 0.1% dilute solution (Treviar™ SC label)
- 1 gallon of 0.1 % dilute solution recommended to treat 1000 ft^2 indoor and outdoor uses (Treviar™ SC label).

Figure A-1. Conceptual model (<u>not to scale</u>) for poultry facility perimeter treatments with broflanilide.

The perimeter of the poultry house that has only pervious ground surfaces is defined by the following equations:

- Area of the perimeter of a 500 ft x 40 ft poultry house treated 18" up and 6" out = (500+500+40+40 ft) x 2 ft = 2160 ft^2
- Where 500 ft is the length of the house, 40 feet is the width of the house and 2 ft (18 inches up wall and 6 inches out from foundation = 24 inches) is the perimeter height.

Assuming **1 house** per acre, the treated area would be 5% of an acre
= (2160 ft^2)/43,560 ft^2 = 0.05

Therefore, the perimeter treatment application rate for a poultry house would be as follows:

Perimeter treatment single application rate: 0.355 lbs a.i./A X 0.05 = 0.018 lbs a.i./A

Perimeter treatment annual application rate: 0.018 lbs a.i./A X 8 treatments/year = 0.14 lbs a.i./A/year

A.4. Summary of Water Modeling of Broflanilide and the USEPA Standard Pond

Estimated Environmental Concentrations for Broflanilide (_ERA_PO_12_5_g) are presented in **Table A-2** for the USEPA standard pond with the MScornSTD field scenario. A graphical presentation **of** the year-to-year acute values is presented in **Figure A-2.** These values were generated with the Pesticide Water Calculator (PWC), Version 2.001. Critical input values for the model are summarized in **Tables A-3** and **A-4**.

This model estimates that about 6.8% of Broflanilide applied to the field eventually reaches the water body. The main mechanism of transport from the field to the water body is by erosion (57.5% of the total transport) followed by runoff (42.5%).

In the water body, pesticide dissipates with an effective water column half-life of 1577.4 days. (This value does not include dissipation by transport to the benthic region; it includes only processes that result in removal of pesticide from the complete system.) The main source of dissipation in the water column is metabolism (effective average half-life = 2011.6 days) followed by photolysis (7318.3 days) and volatilization (4953371 days).

In the benthic region, pesticide dissipation is negligible (2051.1 days). The main source of dissipation in the benthic region is metabolism (effective average half-life = 2051.1 days). The vast majority of the pesticide in the benthic region (99.79%) is sorbed to sediment rather than in the pore water.

Table A-2. Estimated Environmental Concentrations (ppb) for Broflanilide

1-day Avg (1-in-10 yr)	5.58
4-day Avg (1-in-10 yr)	5.58
21-day Avg (1-in-10 yr)	5.53
60-day Avg (1-in-10 yr)	5.49
365-day Avg (1-in-10 yr)	4.69
Entire Simulation Mean	3.36

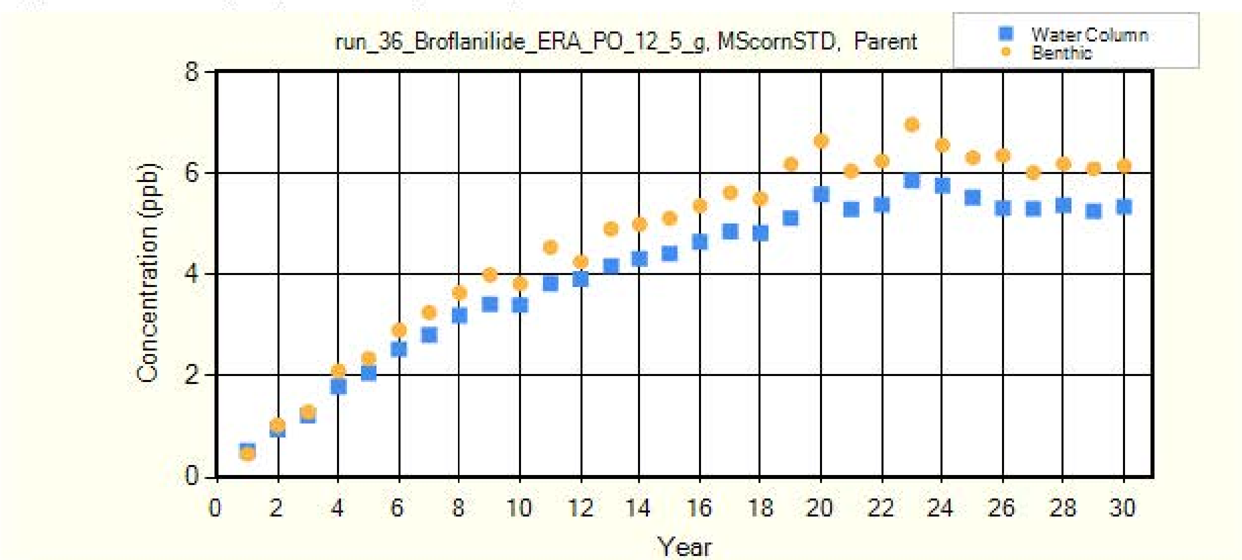
Table A-3. Summary of Model Inputs for Broflanilide

Scenario	MScornSTD
Cropped Area Fraction	1
Kd (ml/g)	177
Water Half-Life (days) @ 20 °C	1934
Benthic Half-Life (days) @ 20 °C	1972
Photolysis Half-Life (days) @ 40 °Lat	80
Hydrolysis Half-Life (days)	0
Soil Half-Life (days) @ 25 °C	2198
Foliar Half-Life (days)	0
Molecular Weight	663.29
Vapor Pressure (torr)	6.60E-11
Solubility (mg/l)	0.71
Henry's Constant	3.32E-09

Table A-4. Application Schedule for Broflanilide

Date (Days Since Emergence)	Type	Amount (kg/ha)	Eff.	Drift
-10	Ground	0.14	1	0

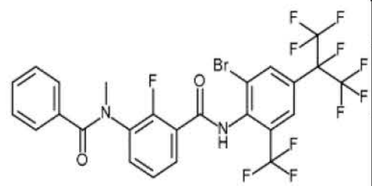
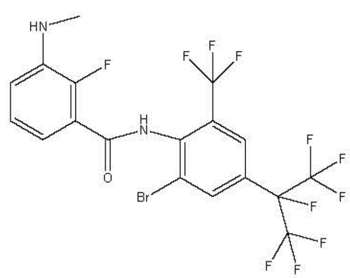
Figure A-2. Yearly Highest 1-day Average Concentrations

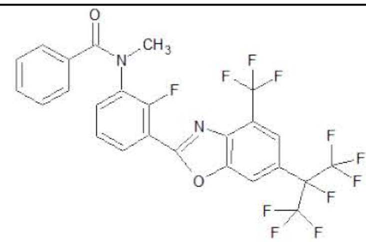
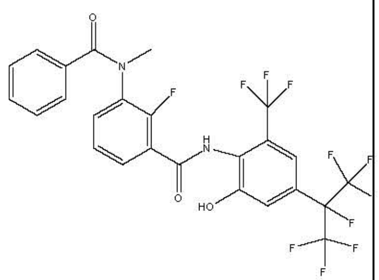


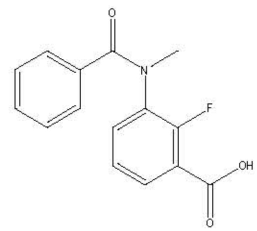
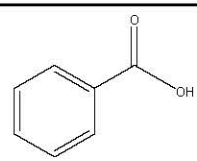
A.5. PWC Input Batch File

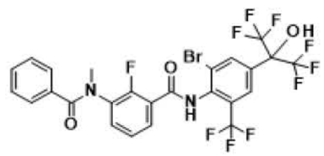
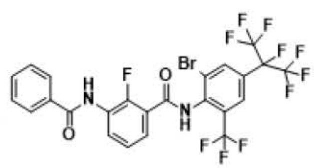
Broflanilide ERA PO batch file.csv

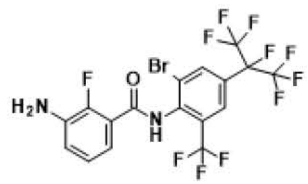
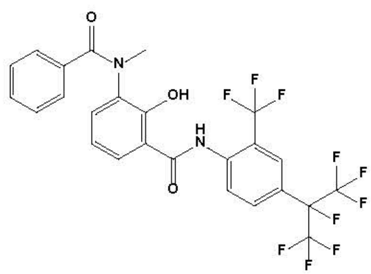
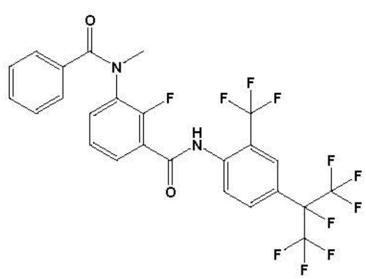
Appendix B. Names and chemical structures of the environmental transformation products of broflanilide

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Study Condition	Maximum %AR (day)	Final %AR (study length)
PARENT COMPOUND							
Broflanilide MCI-8007 BAS 450 I BASF Reg. No. 5672774	*N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(*N*-methylbenzamido)benzamide **CAS#:** 1207727-04-5 **Formula:** $C_{25}H_{14}BrF_{11}N_2O_2$ **MW:** 663.28 g/mol **SMILES Code:** CN(C1=CC=CC(=C1F)C(=O)NC2=C(C=C(C=C2Br)C(C(F)(F)F)(C(F)(F)F)F)C(F)(F)F)C(=O)C3=CC=CC=C3		Hydrolysis	50111328	pH 4, 7 and 9 @ 50°C	-	-
			Aqueous photolysis	50111329	pH 7 @ 25°C	-	-
				50111330	pH 5,7 & 9 @ 25°C	-	-
			Soil photolysis	50211429	Silt Loam	-	-
			Aerobic aquatic	50211437	Brandywine Creek Sediment	-	-
					Choptank River Sediment	-	-
			Anaerobic aquatic	50211438	Brandywine Creek Sediment	-	-
					Choptank River Sediment	-	-
			Aerobic soil	50211427	Centerville Clay, CA	-	-
				50211430	Drummer silty clay loam, IL		
					Norfolk sandy loam, NC		
					Falaya Silt loam, TN		
			Anaerobic soil	50211428	Centerville Clay, CA	-	-
					Drummer silty clay loam, IL		
					Norfolk sandy loam, NC		
					Falaya Silt loam, TN		
MAJOR TRANSFORMATION PRODUCTS							
DC-8007 BASF Reg. No. 5936907	*N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(methylamino)benzamide **CAS#:** N/A **Formula:** $C_{18}H_{10}BrF_{11}N_2O$ **MW:** 559.17 g/mol **SMILES Code:**		Aqueous photolysis	50111329 50111330	pH 5@ 25°C pH 7 @ 25°C pH 9@ 25°C	1.0 (1) ND [1] 1.3 (0)	ND (16) ND ND (16)
			Aerobic aquatic	50211437	Brandywine Creek Sediment	**11.8 (273)**	9.9 (365)
			Anaerobic aquatic	50211438	Brandywine Creek Sediment	**18.2 (365)**	**18.2 (365)**
			Anaerobic soil	50211438	Drummer silty clay loam, IL	**71.7 (363)**	**71.7 (363)**

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Study Condition	Maximum %AR (day)	Final %AR (study length)
	CNc1cccc(C(=O)Nc2c(Br)cc(cc2C(F)(F)F)C(F)(C(F)(F)F)C(F)(F)F)c1F						
AB-oxa BASF Reg. No. 5959600	*N*-{2-fluoro-3-[6-(perfluoropropan-2-yl)-4-(trifluoromethyl)-1,3-benzooxazol-2-yl]phenyl}-*N*-methylbenzamide **CAS#:** N/A **Formula:** $C_{25}H_{13}F_{11}N_2O_2$ **MW:** 582.37 g/mol **SMILES Code:** CN(C(=O)c1ccccc1)c2cccc(c2F)c3oc4cc(cc(c4n3)C(F)(F)F)C(F)(C(F)(F)F)C(F)(F)F		Aqueous photolysis	50111329 50111330	pH 5@ 25°C pH 7 @ 25°C pH 9@ 25°C	6.9 (6) 6.1 (12) **37.6 (3)**	2.1 (16) 4.7 (16) 1.3 (16)
S(Br-OH)-8007 BASF Reg. No. 5959595	2-fluoro-*N*-[4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)-2-hydroxy-6-(trifluoromethyl)phenyl]-3-(*N*-methylbenzamido) benzamide **CAS#:** N/A **Formula:** $C_{25}H_{15}F_{11}N_2O_3$ **MW:** 600.38 g/mol **SMILES Code:** CN(C(=O)c1ccccc1)c2cccc(C(=O)Nc3c(O)cc(cc3C(F)(F)F)C(F)(C(F)(F)F)C(F)(F)F)c2F		Aqueous photolysis	50111329 50111330	pH 5@ 25°C pH 7 @ 25°C pH 9@ 25°C	**14.3(9)** ND 5.5 (9)	**11.4 (16)** ND 1.0 (16)

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Study Condition	Maximum %AR (day)	Final %AR (study length)
MFBA	2-fluoro-3-(N-methylbenzamido)benzoic acid **CAS#:** N/A **Formula:** $C_{15}H_{12}FNO_3$ **MW:** 273.26 g/mol **SMILES Code:** CN(C(=O)c1ccccc1)c2cccc(C(=O)O)c2F		Aqueous photolysis	50111329 50111330	pH 5@ 25°C pH 7 @ 25°C pH 9@ 25°C	**19.7 (16)** ND **25.6 (16)**	**19.7 (16)** ND **25.6 (16)**
Benzoic acid BASF Reg. No. 4005129	**CAS#:** 65-85-0 **Formula:** $C_7H_6O_2$ **MW:** 122.1 g/mol **SMILES Code:** OC(=O)c1ccccc1		Aqueous photolysis	50111329 50111330	pH 5@ 25°C pH 7 @ 25°C pH 9@ 25°C	**25.7 (13)** ND **43.5 (9)**	**25.6 (16)** ND **42.9 (16)**
Carbon dioxide	**CAS#**: 124-38-9 **Formula**: CO_2 **MW:** 44.0 g/mol **SMILE Code:** **SMILES:** C(=O)=O	O=C=O	Aqueous photolysis	50111329 50111330	pH 5-9 @ 25°C	<10.0 (16)	<10.0 (16)
			Aerobic aquatic	50211437	Brandywine Creek Sediment	**15.4 (365)**	**15.4 (365)**
			Anaerobic aquatic	50211438	Brandywine Creek Sediment	<5.0 (365)	<1.0 (365)
			Aerobic soil	50211430	Norfolk sandy loam, NC	1.2 (365)	1.2 (365)
			Anaerobic soil	50211438	Drummer silty clay loam, IL	<2.0 (365)	<2.0 (365)
Unextracted Residues	N/A	N/A	Soil photolysis	50211429	Silt Loam	<5.0 (14)	<5.0 (14)
			Aerobic aquatic	50211437	Choptank River Sediment	**14.2 (365)**	**14.2 (365)**
			Anaerobic aquatic	50211438	Brandywine Creek Sediment	<10.0 (365)	<10.0 (365)
			Aerobic soil	50211430	Norfolk sandy loam, NC	**12.9 (365)**	**12.9 (365)**

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Study Condition	Maximum %AR (day)	Final %AR (study length)
			Anaerobic soil	50211438	All soil samples	<10 (365)	<10 (365)
MINOR TRANSFORMATION PRODUCTS							
S(PFP-OH)-8007 BASF Reg. No. 5959598	*N*-[2-bromo-4-(1,1,1,3,3,3-hexafluoro-2-hydroxypropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(*N*-methylbenzamido)benzamide **CAS#:** N/A **Formula:** $C_{25}H_{15}BrF_{10}N_2O_3$ **MW:** 661.29 g/mol **SMILES Code:** CN(C(=O)c1ccccc1)c2cccc(C(=O)Nc3c(Br)cc(cc3C(F)(F)F)C(O)(C(F)(F)F)C(F)(F)F)c2F		Aqueous photolysis	50111329 50111330	pH 5-9 @ 25°C	8.3 (6)	5.5 (16)
			Aerobic soil	50211427	Centerville Clay, CA	1.1 (0)	ND (365)
				50211430	Norfolk sandy loam, NC	1.0 (15)	0.5 (365)
			Anaerobic soil	50211438	Centerville Clay, CA	3.9 (14)	ND[1] (363)
DM-8007 BASF Reg. No. 5856361	3-benzamido-*N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluorobenzamide **CAS#:** N/A **Formula:** $C_{24}H_{12}BrF_{11}N_2O_2$ **MW:** 649.25 g/mol **SMILES Code:** N(C(=O)C1=CC=CC=C1)(C2=C(C(=CC=C2)C(=O)NC3=C(C=C(C=C3Br)C(O)(C(F)(F)F)C(F)(F)F)C(F)(F)F)F)[H]		Soil photolysis	50211429	Silt Loam	4.2 (6)	2.6 (14)
			Aerobic soil	50211427	Centerville Clay, CA	1.6 (91)	1.1 (365)
			Anaerobic soil	50211438	Drummer silty clay loam, IL	1.5 (30)	ND (363)

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Study Condition	Maximum %AR (day)	Final %AR (study length)
DC-DM-8007 BASF Reg. No. 5936906	3-amino-*N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluorobenzamide **CAS#:** N/A **Formula:** $C_{17}H_8BrF_{11}N_2O$ **MW:** 545.15 g/mol **SMILES Code:** CNc1cccc(C(=O)Nc2c(Br)cc(cc2C(F)(F)F)C(F)(C(F)(F)F)C(F)(F)F)c1F		Aerobic soil	50211430	Norfolk sandy loam, NC	0.9 (259)	ND (365)
S(F-OH)-8007 BASF Reg. No. 5959597	*N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-hydroxy-3-(*N*-Methylbenzamido)benzamide **CAS#:** N/A **Formula:** $C_{25}H_{15}BrF_{10}N_2O_3$ **MW:** 661.29 g/mol **SMILES Code:** CN(C(=O)c1ccccc1)c2cccc(C(=O)Nc3ccc(cc3C(F)(F)F)C(F)(C(F)(F)F)C(F)(F)F)c2O		Aqueous photolysis	50111330	pH 9 @ 25°C	3.8 (6)	1.7 (16)
DBr-8007 BASF Reg. No. 5959596	2-fluoro-3-(N-methylbenzamido)-N-[4-(perfluoropropan-2-yl)-2-(trifluoromethyl)phenyl]benzamide **CAS#:** N/A **Formula:** $C_{25}H_{15}F_{11}N_2O_2$ **MW:** 584.4 g/mol **SMILES Code:**		Aqueous photolysis	50111329 50111330	pH 5@ 25°C pH 7 @ 25°C pH 9@ 25°C	3.8 (2) ND 3.8 (6)	0.2 (16) ND 0.7 (16)

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Study Condition	Maximum %AR (day)	Final %AR (study length)
	CN(C(=O)c1ccccc1)c2cccc(C(=O)Nc3ccc(cc3C(F)(F)F)C(F)(C(F)(F)F)C(F)(F)F)c2F						
UNIDENTIFIED RESIDUES							
Total Unidentified Extracted Residues (UER) [2]	N/A	N/A	Hydrolysis	50111328	pH 4, 7 and 9 @ 50°C	<10.0 (5)	<10.0 (5)
			Aqueous photolysis	50111330	pH 5 @ 25°C pH 9 @ 25°C	**45.4 (16)** **64.8 (16)**	**45.4 (16)** **64.8 (16)**
			Aerobic aquatic	50211437	Choptank River Sediment	<10.0 (365)	<10.0 (365)
			Anaerobic aquatic	50211438	Brandywine Creek Sediment	<5.0 (365)	<5.0 (365)
			Aerobic soil	50211427	Centerville Clay, CA	1.9 (365)	1.9 (365)
			Anaerobic soil	50211438	Drummer silty clay loam, IL	<5.0 (365)	<5.0 (365)

Bolded when appearing at >10%

- = Not applicable

[1] ND = Not Detected

[2] UER consisted of minor degradates, each of which were <10% of the applied.

Appendix C. KABAM Modeling Output

Chemical Specific Inputs

Table 1. Chemical characteristics of Broflanilide.		
Characteristic	**Value**	**Comments/Guidance**
Pesticide Name	**Broflanilide**	**Required input**
Log K_{OW}	**5.2**	**Required input** Enter value from acceptable or supplemental study submitted by registrant or available in scientific literature.
K_{OW}	**158489**	No input necessary. This value is calculated automatically from the Log K_{OW} value entered above.
K_{OC} (L/kg OC)	**7606**	**Required input** Input value used in PRZM/EXAMS to derive EECs. Follow input parameter guidance for deriving this parameter value (USEPA 2002).
Time to steady state (T_S; days)	**45**	No input necessary. This value is calculated automatically from the Log K_{OW} value entered above.
Pore water EEC (µg/L)	**3.55**	**Required input** Enter value generated by PRZM/EXAMS benthic file. PRZM/EXAMS EEC represents the freely dissolved concentration of the pesticide in the pore water of the sediment. The appropriate averaging period of the EEC is dependent on the specific pesticide being modeled and is based on the time it takes for the chemical to reach steady state. Select the EEC generated by PRZM/EXAMS which has an averaging period closest to the time to steady state calculated above. In cases where the time to steady state exceeds 365 days, the user should select the EEC representing the average of yearly averages. The peak EEC should not be used.

Water Column EEC (µg/L)	**3.41**	**Required input** Enter value generated by PRZM/EXAMS water column file. PRZM/EXAMS EEC represents the freely dissolved concentration of the pesticide in the water column. The appropriate averaging period of the EEC is dependent on the specific pesticide being modeled and is based on the time it takes for the chemical to reach steady state. The averaging period used for the water column EEC should be the same as the one selected for the pore water EEC (discussed above).

Table 2. Input parameters for rate constants. "calculated" indicates that model will calculate rate constant.

Trophic level	**k_1 (L/kg*d)**	**k_2 (d^{-1})**	**k_D (kg-food/kg-org/d)**	**k_E (d^{-1})**	**k_M* (d^{-1})**
phytoplankton	calculated	calculated	0*	0*	0
zooplankton	calculated	calculated	calculated	calculated	0
benthic invertebrates	calculated	calculated	calculated	calculated	0
filter feeders	calculated	calculated	calculated	calculated	0
small fish	calculated	calculated	calculated	calculated	0
medium fish	calculated	calculated	calculated	calculated	0
large fish	calculated	calculated	calculated	calculated	0

* Default value is 0.
k_1 and k_2 represent the uptake and elimination constants respectively, through respiration.

k_D and k_E represent the uptake and elimination constants, respectively, through diet.

k_M represents the metabolism rate constant.

Table 3. Mammalian and avian toxicity data for Broflanilide. These are required inputs.

Animal	Measure of effect (units)	Value	Species	If selected species is "other," enter body weight (in kg) here.
Avian	LD_{50} (mg/kg-bw)	>2000	mallard duck	
	LC_{50} (mg/kg-diet)	>5000	Northern bobwhite quail	
	NOAEC (mg/kg-diet)	29.7	mallard duck	
	Mineau Scaling Factor	1.15	Default value for all species is 1.15 (for chemical specific values, see Mineau et al. 1996).	
Mammalian	LD_{50} (mg/kg-bw)	>5000	laboratory rat	
	LC_{50} (mg/kg-diet)	N/A	other	
	Chronic Endpoint	300	laboratory rat	
	units of chronic endpoint*	ppm		

Poultry house perimeter spray (0.02 lbs a.i./A, 8x)

Max Water Column Concentration (3.41 µg/L)

Max Pore Water Concentration (3.55 µg/L)

Table 16. Calculation of RQ values for mammals and birds consuming fish contaminated by Broflanilide.

Wildlife Species	Acute		Chronic	
	Dose Based	Dietary Based	Dose Based	Dietary Based
Mammalian				
fog/water shrew	#VALUE!	N/A	0.410	0.074
rice rat/star-nosed mole	#VALUE!	N/A	0.538	0.079
small mink	#VALUE!	N/A	0.926	0.148
large mink	#VALUE!	N/A	**1.024**	0.148
small river otter	#VALUE!	N/A	**1.102**	0.148
large river otter	#VALUE!	N/A	**1.898**	0.236
Avian				
sandpipers	#VALUE!	#VALUE!	N/A	0.804
cranes	#VALUE!	#VALUE!	N/A	0.915
rails	#VALUE!	#VALUE!	N/A	0.956
herons	#VALUE!	#VALUE!	N/A	**1.120**
small osprey	#VALUE!	#VALUE!	N/A	**1.498**
white pelican	#VALUE!	#VALUE!	N/A	**2.384**

Poultry Manure Field Applications Results

Poultry litter soil amendment (0.125 lbs a.i./A, 1x)
Max Water Column Concentration (5.58 µg/L)
Max Pore Water Concentration (6.55 µg/L)

Table 16. Calculation of RQ values for mammals and birds consuming fish contaminated by Broflanilide.

Wildlife Species	Acute		Chronic	
	Dose Based	Dietary Based	Dose Based	Dietary Based
Mammalian				
fog/water shrew	#VALUE!	N/A	0.675	0.121
rice rat/star-nosed mole	#VALUE!	N/A	0.885	0.130
small mink	#VALUE!	N/A	**1.526**	0.244
large mink	#VALUE!	N/A	**1.686**	0.244
small river otter	#VALUE!	N/A	**1.814**	0.244
large river otter	#VALUE!	N/A	**3.119**	0.388
Avian				
sandpipers	#VALUE!	#VALUE!	N/A	**1.323**
cranes	#VALUE!	#VALUE!	N/A	**1.507**
rails	#VALUE!	#VALUE!	N/A	**1.573**
herons	#VALUE!	#VALUE!	N/A	**1.845**
small osprey	#VALUE!	#VALUE!	N/A	**2.467**

white pelican	#VALUE!	#VALUE!	N/A	**3.918**

Poultry litter soil amendment (0.08 lbs a.i./A, 1x)

Max Water Column Concentration (3.59 μg/L)

Max Pore Water Concentration (4.21 μg/L)

Table 16. Calculation of RQ values for mammals and birds consuming fish contaminated by Broflanilide.

Wildlife Species	Acute		Chronic	
	Dose Based	Dietary Based	Dose Based	Dietary Based
Mammalian				
fog/water shrew	#VALUE!	N/A	0.434	0.078
rice rat/star-nosed mole	#VALUE!	N/A	0.569	0.084
small mink	#VALUE!	N/A	0.981	0.157
large mink	#VALUE!	N/A	**1.084**	0.157
small river otter	#VALUE!	N/A	**1.167**	0.157
large river otter	#VALUE!	N/A	**2.006**	0.250
Avian				
sandpipers	#VALUE!	#VALUE!	N/A	0.851

cranes	#VALUE!	#VALUE!	N/A	0.970
rails	#VALUE!	#VALUE!	N/A	**1.012**
herons	#VALUE!	#VALUE!	N/A	**1.187**
small osprey	#VALUE!	#VALUE!	N/A	**1.587**
white pelican	#VALUE!	#VALUE!	N/A	**2.520**

Poultry litter soil amendment (0.04 lbs a.i./A, 1x)
Max Water Column Concentration (1.80 µg/L)
Max Pore Water Concentration (2.10 µg/L)

Table 16. Calculation of RQ values for mammals and birds consuming fish contaminated by Broflanilide.

Wildlife Species	Acute		Chronic	
	Dose Based	Dietary Based	Dose Based	Dietary Based
Mammalian				
fog/water shrew	#VALUE!	N/A	0.218	0.039
rice rat/star-nosed mole	#VALUE!	N/A	0.285	0.042
small mink	#VALUE!	N/A	0.492	0.079
large mink	#VALUE!	N/A	0.544	0.079
small river otter	#VALUE!	N/A	0.585	0.079
large river otter	#VALUE!	N/A	**1.006**	0.125
Avian				
sandpipers	#VALUE!	#VALUE!	N/A	0.427

cranes	#VALUE!	#VALUE!	N/A	0.486
rails	#VALUE!	#VALUE!	N/A	0.507
herons	#VALUE!	#VALUE!	N/A	0.595
small osprey	#VALUE!	#VALUE!	N/A	0.795
white pelican	#VALUE!	#VALUE!	N/A	**1.263**

Poultry litter soil amendment (0.02 lbs a.i./A, 1x)
Max Water Column Concentration (0.88 µg/L)
Max Pore Water Concentration (1.03 µg/L

Table 16. Calculation of RQ values for mammals and birds consuming fish contaminated by Broflanilide.

Wildlife Species	Acute		Chronic	
	Dose Based	Dietary Based	Dose Based	Dietary Based
Mammalian				
fog/water shrew	#VALUE!	N/A	0.106	0.019
rice rat/star-nosed mole	#VALUE!	N/A	0.140	0.021
small mink	#VALUE!	N/A	0.241	0.039
large mink	#VALUE!	N/A	0.266	0.039
small river otter	#VALUE!	N/A	0.286	0.039
large river otter	#VALUE!	N/A	0.492	0.061
Avian				
sandpipers	#VALUE!	#VALUE!	N/A	0.209

cranes	#VALUE!	#VALUE!	N/A	0.238
rails	#VALUE!	#VALUE!	N/A	0.248
herons	#VALUE!	#VALUE!	N/A	0.291
small osprey	#VALUE!	#VALUE!	N/A	0.389
white pelican	#VALUE!	#VALUE!	N/A	0.618